

# Background Analysis for National HTA Strategy for Lithuania

Focus on Medical Devices



Ludwig Boltzmann Institut  
Health Technology Assessment

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**Conflict of Interest**

All contributing authors declare that they have no conflicts of interest according to the Uniform Requirements of Manuscripts Statement of Medical Journal Editors ([www.icmje.org](http://www.icmje.org))

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## List of abbreviations

|                  |  |              |  |
|------------------|--|--------------|--|
| AETS.....        | Agencia de Evaluacion de Tecnologias Sanitarias, Spain   | DAHTA.....   | German Agency of Health Technology Assessment  |
| AETSA .....      | Andalusian Agency for Health Technology Assessment, Spain  | DARE .....   | Database of Abstracts of Reviews of Effects, United Kingdom  |
| AGENAS.....      | Agency for Regional Healthcare, Italy  | DCP .....    | Decentralised Procedure  |
| AIDS .....       | Acquired Immune Deficiency Syndrome  | DRG.....     | Diagnosis-related group  |
| AIFA .....       | Italian Medicines Agency   | DUK .....    | Danube University Krems, Austria   |
| AMNOG.....       | German Pharmaceuticals Market Reorganisation Act (Gesetz zur Neuordnung des Arzneimittelmarktes)                                     | EACCME ..... | European Accreditation Council for Continuous Medical Education  |
| AOTMiT .....     | Agency for Health Technology Assessment and Tariff System, Poland  | EC .....     | European Council   |
| AQuAS .....      | Agencia de Qualitat i Avaluacio Sanitaries de Catalunya, Spain   | EEA.....     | European Economic Area   |
| ASSR.....        | ..Agenzia Sanitaria e Sociale Regionale (Regional Agency for Health and Social Care), Italy  | ELGK .....   | . Swiss Federal Commission for Medical Benefits and Principles (Eidgenössische Leistungs- und Grundsatzkommission) |
| AVALIA-T .....   | Galician Agency for HTA, Spain   | EMA .....    | European Medicines Agency  |
| AWMF .....       | Association of Scientific Medical Societies in Germany (Arbeitsgemeinschaft der Wissenschaftlichen Medizinischen Fachgesellschaften) | ERDF .....   | European Regional Development Fund   |
| BAG.....         | Bundesamt für Gesundheit (Swiss Federal Office of Public Health)   | ESF .....    | European Social Fund   |
| CE marking ..... | Conformité Européenne  | FinOHTA..... | Finnish Office for Health Technology Assessment  |
| CEM.....         | Cellule d'expertise medicale, Luxembourg   | FTE.....     | Full-time employee   |
| CEDIT .....      | Committee for Evaluation and Dissemination of Innovative Technologies, France  | G-BA.....    | German Federal Joint Committee (Gemeinsamer Bundesausschuss)   |
| CEO.....         | Chief Executive Officer  | GDP.....     | Gross Domestic Product   |
| CHIF .....       | Compulsory Health Insurance Fund   | GMP .....    | Good Manufacturing Practice  |
| CIRS.....        | Critical Incident Reporting System   | GÖG.....     | Gesundheit Österreich, Austria   |
| CME.....         | Continuing medical education   | GRADE .....  | Grades of Recommendation, Assessment, Development and Evaluation   |
| CoI.....         | Conflict of Interest   | HAS .....    | Haute Autorite de Sante, France  |
| CPO .....        | Central Procurement Organisation   | HCNA.....    | Health Care Needs Assessment   |
| CRD .....        | Centre for Reviews and Dissemination, United Kingdom   | HIQA.....    | Health Information and Quality Authority, Ireland  |
|                  |  | HTA.....     | Health Technology Assessment   |
|                  |  | HTA-HSR/     |  |
|                  |  | DHTA.....    | HTA & Health Services Research Department of HTA   |
|                  |  | HQO .....    | Health Quality Ontario, Canada   |
|                  |  | INAHTA.....  | International Network of Agencies for Health Technology Assessment   |
|                  |  | IoH.....     | Institute of Hygiene, Lithuania  |

|               |   |               |   |
|---------------|---|---------------|---|
| IQWiG.....    | Institute for Quality and Efficiency in Health Care, Germany (Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen) | NOKC.....     | Norwegian Knowledge Centre for the Health Services                            |
| KCE.....      | Belgian Federal Health Care Knowledge Centre  | OHTAC .....   | Ontario Health Technology Advisory Committee, Canada                          |
| LBI-HTA ..... | Ludwig Boltzmann Institute for Health Technology Assessment, Austria  | OSTEBA.....   | Basque Office for HTA, Spain  |
| LNHS .....    | Lithuanian National Health System   | OTC .....     | Over-the-counter  |
| LUHS .....    | Lithuanian University of Health Sciences  | PICO.....     | Patient-Intervention-Control-Outcome  |
| MA.....       | Marketing Authorisation   | PET .....     | Positron emission tomography  |
| MAH .....     | Market Authorization Holders  | PRISMA .....  | Preferred Reporting Items for Systematic Reviews and Meta-Analyses            |
| MEDAS.....    | Vilnius university and Lithuanian university of health sciences information system  | REA .....     | Relative Effectiveness Assessment   |
| METAS .....   | SVEIDRA Subsystem   | SBU.....      | Swedish Council on HTA in Health Care   |
| MoH .....     | Ministry of Health  | SEC .....     | Sveikatos ekonomikos centras. Lithuania                                       |
| MRP .....     | Mutual Recognition Procedure  | SHAA .....    | State Healthcare Accreditation Agency under the Ministry of Health, Lithuania |
| MS .....      | Member State  | SMCA .....    | State Medicines Control Agency under the Ministry of Health, Lithuania        |
| MUMM.....     | Managed uptake of medical methods Programme, Finland  | SNHTA.....    | Swiss Network for Health Technology Assessment                                |
| MTU-SFOPH..   | Medical Technology Unit – Swiss Federal Office of Public Health   | SVEIDRA.....  | NHIF information system, Lithuania  |
| NB .....      | Notified Body   | STA.....      | Single Technology Assessment  |
| NETSCC.....   | NIHR Evaluation, Trials and Studies Coordinating Centre, United Kingdom   | TAVI.....     | Transcatheter Aortic Valve Implantation                                       |
| NHIF.....     | National Health Insurance Fund under the Ministry of Health, Lithuania  | THL .....     | National Institute for Health and Welfare, Finland                            |
| NHS.....      | National Health Service, England  | UAB .....     | Private Limited Liability Company (in Lithuanian)                             |
| NHS-EED.....  | National Health Service Economic Evaluation Database, United Kingdom  | UVT-HTA ..... | HTA Unit in A. Gemelli Teaching Hospital, Italy                               |
| NICE.....     | National Institute for Health and Care Excellence, United Kingdom   | VU .....      | Vilnius University  |
|               |   | ZIN .....     | Dutch National Health Care Institute (Zorginstituut Nederland)                |



## Leitmotif and Quote

The art of decision-making is part of a political culture.  
Changes in culture need time and involvement of all affected.

***“To introduce HTA in the decision-making process is like cultivating a garden in a snowstorm”.***

Günter Jonitz (president of Berlin´ chamber of physicians),  
Oct. 28<sup>th</sup> 2009



# 1 Introduction

## 1.1 Health Technology Assessment (HTA) – What is it and what for to use it?

Health Technology Assessment, abbreviated as HTA, is defined as [1] by EUnetHTA:

*“a multidisciplinary process that summarizes information about the medical, social, economic and ethical issues related to the use of a health technology in a systematic, transparent, unbiased, robust manner. **Its aim is to inform the formulation of safe, effective, health policies that are patient focused and seek to achieve best value.***

*Despite its policy goals, HTA must always be firmly rooted in research and the scientific method”.*

Health Technologies are e.g.

- ✳ Diagnostic and treatment methods such drugs, devices, surgical interventions, laboratory tests or biomarker
- ✳ Medical equipment such as catheter laboratories and positron-Emissions-Tomography
- ✳ Rehabilitation and prevention methods such as occupational therapy psychotherapy or dietary interventions
- ✳ Public Health programs such as screening, vaccinations, primary and secondary prevention programs such as interventions against alcohol abuse or smoking,
- ✳ Organizational and supportive systems within which health care is provided such as checklists, IT and telemedicine or even advanced training.

Health Technology Assessment can be applied for informing health policy on

- ✳ investments in new equipment
- ✳ placement and planning of big devices
- ✳ inclusion of new interventions in benefit catalogue or
- ✳ disinvestment of obsolete (old or ineffective) interventions
- ✳ the available evidence for clinical guidelines for quality assurance
- ✳ relative (cost-) effectiveness of alternative interventions
- ✳ appropriate use of medical interventions
- ✳ prioritization in resource allocation

and can be of use – more generally – for

- ✳ controlled diffusion of high cost or high volume technologies (coverage with evidence development)
- ✳ resource allocation based on evidence of best value
- ✳ cost-containment in low value areas
- ✳ increasing equitable access to effective services
- ✳ increasing efficiency in provision of services
- ✳ decreasing practice variations
- ✳ improving quality

and therefore providing input to a sustainable health care of high value for all citizen.

health policy decision  
support for best value

systematic  
transparent,  
unbiased  
interdisciplinary

broad definition of  
“health technology”

applied in many areas  
of decision making

for a sustainable  
health care

|   |   |
|---|---|
| <b>distinction:</b><br><b>HTA vs. decision-making</b> | <p>It must be stressed that HTA is per definitionem a decision-support tool (only):</p> <p>HTA does NOT replace (sometimes difficult) decisions, but makes <b>argumentation under pressure from interest groups</b> a lot easier.</p> <p>HTA „opens eyes“, that (lack of or marginal) effectiveness and (a critical) risk-benefit ratio is in the centre of consideration and not economics.</p> <p>HTA requires a certain „civilized <b>courage</b>“ to <b>question the actual innovative and transformative nature of new technologies</b> and requires creativity to invent new policy instruments to implement HTA.</p> |
| <b>decisions:</b><br><b>value-judgements</b>          | <p><b>In contrast, decisions</b> also always involve value-judgements such as thresholds for appropriateness or medical need or for a cost-benefit ratio or clear-cut distinction between patient-oriented need and provider-induced demand, but also access and equity issues in planning etc.</p>   |

## 1.2 European Health Technology Assessment (HTA) – Why collaborating?

|   |  |
|---|--|
| <b>2004 EU-Commission:</b><br><b>HTA is political priority</b>  | <p>In 2004, the European Commission and Council of Ministers targeted Health Technology Assessment (HTA) as “a political priority”, recognizing “(...) an urgent need for establishing a sustainable European network on HTA” [1].</p>   |
| <b>2011 Cross-border Directive:</b>   | <p>In 2011, the “Cross-border Directive” [2] was published, writing in Art 15 that on Cooperation on health technology assessment</p>  |
| <b>cooperation in HTA to avoid duplication</b>  | <ol style="list-style-type: none"> <li>1. The Union shall support and facilitate cooperation and the exchange of scientific information among Member States within a voluntary network connecting national authorities or bodies responsible for health technology assessment designated by the Member States. The Member States shall communicate their names and contact details to the Commission. The members of such a health technology assessment network shall participate in, and contribute to, the network’s activities in accordance with the legislation of the Member State where they are established. That network shall be based on the principle of good governance including transparency, objectivity, independence of expertise, fairness of procedure and appropriate stakeholder consultations.</li> <li>2. The objectives of the health technology assessment network shall be to: <ol style="list-style-type: none"> <li>a. support cooperation between national authorities or bodies;</li> <li>b. support Member States in the provision of objective, reliable, timely, transparent, comparable and transferable information on the relative efficacy as well as on the short- and long-term effectiveness, when applicable, of</li> <li>c. health technologies and to enable an effective exchange of this information between the national authorities or bodies;</li> <li>d. support the analysis of the nature and type of information</li> <li>e. that can be exchanged;</li> <li>f. avoid duplication of assessments.</li> </ol> </li> </ol> |
| <b>governance:</b><br><b>transparency,</b><br><b>objectivity,</b><br><b>independence of expertise,</b><br><b>fairness of procedure,</b><br><b>appropriate stakeholder consultations</b> |  |

3. In order to fulfil the objectives set out in paragraph 2, the network on health technology assessment may receive Union aid. Aid may be granted in order to:
  - a. contribute to the financing of administrative and technical support;
  - b. support collaboration between Member States in developing and sharing methodologies for health technology assessment including relative effectiveness assessment;
  - c. contribute to the financing of the provision of transferable scientific information for use in national reporting and case studies commissioned by the network;
  - d. facilitate cooperation between the network and other relevant institutions and bodies of the Union;
  - e. facilitate the consultation of stakeholders on the work of the network.

**support by EC for collaboration**

..... (4. to 6. on procedures and management)

7. Measures adopted pursuant to this Article shall not interfere with Member States' competences in deciding on the implementation of health technology assessment conclusions and shall not harmonise any laws or regulations of the Member States and shall fully respect the responsibilities of the Member States for the organization and delivery of health services and medical care.

**collaborative HTA shall NOT interfere with MS competences in decision-making**

A Commission call was answered in 2005 by a group of 35 organizations throughout Europe which led to the activities of the EUnetHTA Project [1]. The consequent activities of the European network for Health Technology Assessment EUnetHTA were organised through establishment of the EUnetHTA Collaboration 2009, the EUnetHTA Joint Action 2010-2012 and EUnetHTA Joint Action 2 2012-2015, EUnetHTA Joint Action 3 2016-2019.

**EUnetHTA: European network for HTA**

For more information on the historical and political background of a sustainable network for HTA in Europe, read [3-7].

## 1.3 A National HTA strategy

The task for this paper, the development of a National HTA-strategy for Lithuania, is based on national needs for HTA within the national regulatory context and European embedding of increased collaboration.

**task: National HTA-strategy in national regulatory context and European embedding**

A strategy is a high level plan to achieve one or more goals and is defined by a comprehensive way to try to pursue political ends. Strategy generally involves

**definition of strategy: plan to achieve one or more goals**

- ✿ setting goals,
- ✿ determining actions to achieve the goals, and
- ✿ mobilising resources to execute the actions.

A strategy describes how the ends (goals) will be achieved by the means (resources). Strategy can be intended or can emerge as a pattern of activity as the organization adapts to its environment. It involves activities such as strategic planning and strategic thinking. Strategy is about shaping the future and is the attempt to get to “desirable ends with available means”. Strategic planning involves the formulation and implementation of the major goals and

initiatives based on consideration of resources and an assessment of the internal and external environments. Strategic planning provides overall direction and involves developing policies and plans designed to achieve these objectives, and then allocating resources to implement the plans. Strategic planning is not static in nature; the models often include a feedback loop to monitor execution and inform the next round of planning.

**National HTA Strategy  
for Lithuania, focus  
medical devices:**

**making a plan for  
activities within the  
given environment**

**general aims**

This document, “The National HTA Strategy for Lithuania, focus medical devices” intends to support the 1<sup>st</sup> process, the formulation by analyzing the environment, making a plan for activities within the given environment, and developing guiding policies. Implementation refers to the action plans taken to achieve the goals established by the guiding policy. This 2<sup>nd</sup> step is left to the owners of “The National HTA Strategy for Lithuania, focus medical devices”, the contractor SHAA/State Health Care Accreditation Agency.

The “National Strategy for HTA in Lithuania, focus medical devices” pursues, based on WHO’s strategy “Health for All” [8], two general aims [9]:

- ✱ to establish a solid and comprehensive (so called “evidence-based”) foundation for decision making for the introduction and utilization of health technologies at all levels in the health care system;
- ✱ to ensure that HTA becomes an integrated part of routine decision making for planning and operational policy within the health care system.

**specific goals of  
National HTA Strategy**

The specific goals of the “National Strategy for HTA in Lithuania, focus medical devices” are

1. To establish a framework to promote (enforce, facilitate) HTA uptake.
2. To establish organizational structures for timely, efficient and good-quality provision of HTA-information that satisfies needs.
3. To increase acceptance and demand for HTA-information by offering tailor-made services.
4. To boost the use of HTA-information.

## 2 Methodology

### 2.1 Analytical framework

The Development of an HTA-strategy for Lithuania, specific focus HTA for Medical Devices will be based on the following analytical framework:

#### 1. Analysis of legal framework and regulatory context of decision-making

- ✧ International examples of legal and regulatory linkage with policy environment
- ✧ Description of Lithuanian health care and decision-making processes

analysis of legal  
framework and  
regulatory context

*Method:* Literature review for examples from countries, detailed analysis of Lithuanian system, interviews with Lithuanian decision-makers

#### 2. Analysis of utilization of HTA in health care and barriers

- ✧ International examples for HTA utilization and applications, but also barriers
- ✧ Analysis of perceived needs and barriers within the Lithuanian health system, and barriers

analysis of utilization  
(need and demand)  
of HTA

*Method:* Literature review for examples, interviews with Lithuanian decision-makers

#### 3. Analysis of HTA institutionalization and financing

- ✧ International examples for HTA embedding in institutions and financing of HTA
- ✧ Analysis of existing and possible HTA embedding and financing in Lithuanian health system

analysis of HTA  
institutionalization  
and financing

*Method:* Literature review for examples, interviews with Lithuanian decision-makers

#### 4. Analysis of human resources and capacity building

- ✧ International examples for training in HTA and capacity building for “emerging” countries
- ✧ Analysis of existing and possible training in HTA and capacity building in Lithuania

analysis of human  
resources and capacity  
building

*Method:* Literature review for examples, interviews with Lithuanian decision-makers

#### 5. Analysis HTA processes and products, special focus assessment of medical devices

- ✧ International examples for good practice in HTA processes and products
- ✧ Analysis for need of establishment of processes and products in Lithuania

analysis HTA processes  
and products

*Method:* Literature review for examples, interviews with Lithuanian HTA providers

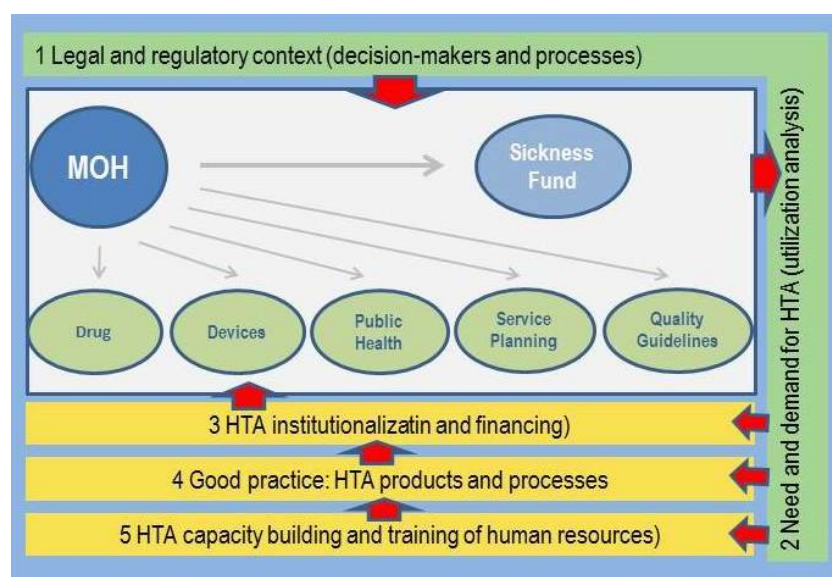


Figure 2.1-1: Generic Analytical Framework for Development of HTA-Strategy for Lithuania

## 2.2 Materials

### 3 sources

For the 5 analytical approaches the following 3 sources were used:

- ✿ Systematic search for HTA strategy papers and extensive hand-searches,
- ✿ Detailed analysis of Lithuanian health care system,
- ✿ Interviews with Lithuanian decision-makers.

### 2.2.1 Literature Search

#### systematic literature search

The systematic literature search was conducted on 08.04.2015 in the following Databases:

#### country reports on HTA implementation

- ✿ Medline via Ovid
- ✿ Embase
- ✿ The Cochrane Library
- ✿ CRD (DARE, NHS-EED, HTA)

#### hand search: 2 national strategy papers

#### from Austria, Denmark

The search yielded 170 hits altogether. After deduplication 148 citations remained for abstract screening. None of the citations reported on a “National HTA Strategy”, but rather broadly on the phase of implementation and utilization of HTA in the different health care systems (Int J TAHC: 2000, Int J TAHC 2009). Two published “National HTA Strategy” papers (see Table 2.2-1) were found by hand-searching (resp. via personal involvement in the Austrian HTA Strategy):



Table 2.2-1: Published National HTA Strategy-papers

|   |
|---|
| Danish National Board of Health ( <i>Sundhedsstyrelsen</i> ):<br>National Strategy for Health Technology<br>Assessment [9, 10] – 1996 (English) |
| GÖG/Gesundheit Österreich:<br>Nationale HTA Strategie [11] – 2009 (German)  |

### 2.2.2 System Analysis

For a detailed analysis of the regulatory and organisational environment a Lithuanian expert in health care analysis (Co-Authors M. Stricka; L. Karnickas) was asked for collaboration. The expert was asked to give support on:

- ✿ Description of Lithuanian legislation and regulation of health care,
- ✿ Description of responsibilities and the decision making processes on public health interventions, hospital services, drugs/devices
- ✿ The landscape of advanced training/capacity building for HTA,
- ✿ Resource evaluation/estimation of FTE already working in HTA,
- ✿ Role of Physicians in Guideline Development

input from  
Lithuanian expert in  
health care analysis

### 2.2.3 Interviews

To tap into local health systems expertise surrounding HTA, 19 experts were interviewed in person in Vilnius and Kaunas in February, May and June of 2015. The interviews centred around Lithuania's key institutions relevant for HTA, i.e. the Ministry of Health/MoH and subordinated institutions: National Health Insurance Fund, State Health Care Accreditation Agency, Institute of Hygiene, State Medicines Control Agency and the University Hospitals in Vilnius and Kaunas (14 experts interviewed). A second focus was put on experts from academia (research, teaching: 2 experts interviewed). Finally experts with first hand health system knowledge not institutionally affiliated were interviewed (3 experts interviews). The initial list of contacts was compiled by the State Health Care Accreditation Agency under the Ministry of Health. Additional contacts resulted from some of the resulting expert interviews. Table 2.2-2 contains the list of the experts interviewed, their institutional affiliation and the date of the personal interview.

19 personal interviews:

MoH and subsidiary  
institutions

academia  
and experts with health  
system experience

Table 2.2-2: Lithuanian Experts interviewed

| Institution  | Person   | Date  |
|--|--|---|
| Seimas of the Republic of Lithuania<br>Committee on Health Affairs | D. Mikutiene<br>Chair  | Referred to<br>MoH  |
| Ministry of Health<br>of the Republic of Lithuania<br>MoH          | L. Vaideliene<br>Vice-Minister<br>Chair HTA Committee  | May 7 <sup>th</sup> , 2015                                |
|  | J. Januševičienė<br>Head of Health Care Accessibility and Acceptability Unit<br>Member HTA Committee | May 7 <sup>th</sup> , 2015<br>June 3 <sup>rd</sup> , 2015 |
|  | K. Auruškevičienė<br>Head of European Union Support Division<br>Member HTA Committee                 | June 4 <sup>th</sup> , 2015                               |

| Institution   | Person   | Date  |
|---|--|---|
| Institutions under the Ministry of Health                 | National Health Insurance Fund NHIF  | G. Kacevičius<br>Acting Director<br>Former member HTA Committee   |
|   | N. Berntotiene<br>Deputy Director for management and organization of work                          | June 3 <sup>rd</sup> , 2015   |
|   | J. Sabaliene<br>Head International Affairs Department  |   |
|   | T. Golubajeva<br>Head Clinical Coding Section<br>Member HTA Committee                              |   |
|   | State Health Care Accreditation Agency SHAA  | N. Ribokiene<br>Director  |
|   |  | P. Morkuniene<br>Chief Specialist for Accreditation   |
|   | Institute of Hygiene Public Health Technology Center – Research and Technology Assessment Unit IOH | R. Janoniene<br>Public Health Technology Center<br>Head of Research and Technology Assessment Unit  |
|   |  | R. Valinteliene<br>Head of Public Health Technology Center  |
|   | State Medicines Control Agency (SMCA)  | G. Barcys<br>Director   |
|   | Vilnius University Hospital Santariskiu Klinikos   | D. Jankauskiene<br>Advisor to Director General of Vilnius University Hospital Santariskiu Clinics   |
| Academia: Lithuanian University of Health Sciences (LUHS) | Hospital of Lithuanian University of Health Sciences (LUHS) Kauno Klinikos                         | M. Štelemekas<br>Member HTA Committee<br>Kaunas Clinics Hospital, Department of Innovation Assessment and Deployment<br>Lithuanian University of Health Sciences<br>Interview delegated by:<br>L. Jaruševičienė<br>Director for Public Health, Research and Education, Lithuanian University of Health Sciences |
|   | Academia: Lithuanian University of Health Sciences (LUHS)  | V. Grabauskas<br>Chancellor of the Medical Academy<br>Council Member<br>Lithuanian University of Health Sciences  |
|   | Academia: Mykolas Romeris University (see also Vilnius University Hospital)                        | D. Jankauskiene<br>Professor, Institute of Political Sciences<br>Faculty of Politics and Management<br>Mykolas Romeris University   |
| Health system knowledge                                   | Health system knowledge  | G. Černiauskas<br>UAB Sveikatos ekonomikos centras (SEC)<br>former Health Minister<br>former Vice-Minister  |
|   | Health system knowledge  | J. Galdikas<br>former Head of SHAA<br>former Health Minister  |
|   | Health system knowledge  | L. Murauskiene<br>First author HiT Lithuania  |

## 3 Background analyses for HTA Strategy

### 3.1 Analysis of legal framework and regulatory context of decision-making

#### 3.1.1 International examples of legal and regulatory linkage with policy environment

The regulatory environment for decision-making in health care is very different across European countries and depending on the main characteristics of health care organisation (Beveridge, Bismarck and mixed systems). The main distinction is between more centralized like in many tax-based NHS/ National Health Service Systems (England, Denmark) or highly decentralized as in some insurance based systems (Austria, Germany). The general rule is that in decentralized systems new (“innovative”) interventions make it faster to the market (providers) than in centralized systems.

Nevertheless the purposes of decisions are almost equal to all systems and the major decision-makers can therefore be analysed in a systematic manner:

- ✿ Who (which institution) is responsible for what kind of decision?
- ✿ Are there regulatory instruments in place to implement the decision?
- ✿ Is the decision binding or recommendatory?

Binding legal requirements that scientific evidence of effectiveness, safety, cost-effectiveness or quality assurance have to be presented before a decision about a public health policy (on screening programme or vaccination) and/or investments (in specialized medical centres or large equipment) and/or reimbursement (in benefit catalogues) is made are – in many countries – rare. Indirect references can be found, however, in some legal texts (e.g. in Austria: “the act of care must be sufficient and appropriate, but the extent of inevitable required not exceeding” [12]) which can be interpreted to stipulate such requirements:

Most HTA-agencies in Europe are advisory bodies and have no regulatory function [5]. This segregation of functions is rooted in the HTA value (and pragmatic necessity) of independence of interest and influence from decision-makers of any kind (see detailed paragraph on independence in 3.3.1). Examples for the legislative foundation and the conscious segregation of functions are England with NICE and Germany with IQWiG.

As written elsewhere HTA is most influential or develops the most impact if it is carried out for concrete decisions:

Influential examples within Europe for

- ✿ HTA for the In-/exclusion in the national hospital-catalogue is the Austrian annual programme [13, 14]
- ✿ HTA for investments and In-/exclusion of regional and local hospital services are the Danish “Mini-HTA” programme [15] and the Finnish “MUMM-Programme” [16]
- ✿ HTA for national drug benefit assessments and according price-negotiations is the German AMNOG [17]

**regulatory environment  
for decision-making**

**analysis:  
responsibility  
for decisions,**

**regulatory instruments  
for implementation of  
decision,**

**nature of decision**

**segregation of  
functions: HTA and  
decision-making**

**influential examples  
for HTA correlated  
with concrete  
decision-making**

**Austria+Denmark:  
national/regional hospital  
benefit-catalogue**

**Germany: drug benefit  
assessments**

|   |   |
|---|---|
| <b>Basque: disinvestment</b>  | ✳ HTA for regional disinvestment decisions is the Basque [18]   |
| <b>Germany: guidelines</b>  | ✳ HTA for national care guidelines is the German AWMF S3 programme [19].  |
|   | ✳ Etc.  |
| <b>negative examples of demand/not need-based planning: PET-devices, Hadron- and proton centers</b> | <p>Due to lack of direct correlations between the impact of evidence-based knowledge and needs-based planning few examples exist in this field of expertise, though highly relevant.</p> <p>✳ Negative example of provider-/demand-driven (not need-based) investments and worldwide are: PET-devices, Hadron-and proton centres.</p> |

Table 3.1-1: Decision-Makers, Policy content and Regulatory Instruments (example: Austria)

| Responsible Institution       | Policy content   | Potential regulatory instruments  | Examples  |
|-------------------------------|--|---|---|
| Ministry of Health            | Immunisation schedule<br>Prevention programs<br>Screening<br>Infrastructure  | (General or age-group specific)<br>In-/exclusion in public immunisation schedule,<br>Investments in prevention programs<br>Investments in early detection<br>Investments in medical infrastructure  | HPV-vaccination,<br>Saisonal influenza vaccination<br>Mother-child care Health checks<br>Mammography or Colon-Screening<br>Hospitals, polyclinics, outpatient services  |
| Ministry of Health            | Hospital financing<br>Hospital services catalogue<br>Additional investments in equipment<br>Planning of big equipment/ specialized services<br>Inpatient Drugs | DRGs or capitation<br>In-/exclusion of additional services<br>hospital catalogue<br>Tariffs<br>Conditional Coverage/Coverage with Evidence Development (Research)<br>Infra-structural requirements for planning<br>Minimal quality-volume requirements for specialized or frequent services<br>Inpatient drug-commissions | Re-calculation of DRGs for new surgical interventions or procedures<br>Planning: TAVI, PET ...<br>Rare interventions: Neurosurgery, transplantation<br>Quality indicators for frequent interventions: Elective surgery in orthopaedics, birth clinics, positive/negative list for inpatient drugs (e.g. onco drugs) |
| Social Insurance Institutions | Outpatient services catalogue<br>Outpatient-drugs  | Outpatient drug-commissions<br>In-/exclusion of additional services<br>Outpatient services benefit catalogue/basket<br>In-/exclusion of new services<br>Fee-for service tariffs<br>Capitation<br>Quality Audits/Pay-for-Performance<br>Conditional Coverage/Coverage with Evidence Development (Research)                 | Positive/negative list for inpatient drugs (e.g. rheuma drugs)<br>Quality indicators for chronic conditions: asthma, diabetes, breast cancer  |
| Social Insurance Institutions | Planning of rehabilitation<br>Planning of long-term care facilities  | Infra-structural requirements for rehab services<br>Access-regulation (thresholds)<br>Outcome measurement   | Severity of illness indicators as appropriateness-criteria for long-term care<br>Quality indicators for outcome assessment after cardio-rehab   |
| Chamber of Physicians         | Quality assurance<br>CME/continuous medical training   | Clinical guidelines<br>Clinical pathways<br>Auditing, benchmarking  | Guidelines for chronic conditions<br>Pathways for stepped care in diagnostics   |
| Regions                       | Maintenance of hospitals and services  | Quality assurance + control<br>Clinical risk-management   | Hygiene management<br>CIRS/Critical Incident Reporting System-installation  |

### 3.1.2 Lithuanian health care system and decision-making processes

#### 3.1.2.1 Introduction to and overview of the Lithuanian health care system and HTA in Lithuania based on expert interviews

Lithuania declared independence from the Soviet Union on March 11<sup>th</sup>, 1990 and joined the European Union on May 1<sup>st</sup>, 2004.

Lithuania has the second highest aged-standardized mortality from all causes in the EU and the highest gender gap in life expectancy at birth. In 2010 men were expected to live 69 years and women 70 years [20]. Lithuania has the lowest self-reported health status in the EU and the poorest health status indicators in the Baltic region [21].

Lithuania spends 6.7% of GDP on health, of which approximately 60% come from statutory health insurance, 11% from tax revenues and 29% from out of pocket payments [22].<sup>1</sup> More than 70% of out of pocket payments are for pharmaceuticals. More than half of statutory health insurance revenue comes from the national budget in the form of transfers for population groups insured by the state (e.g. pensioners, children, individuals on parental leave) [20].

Overarching health policies are set by Parliament and government [22]. Also after independence Lithuania's health care system remained centralized [21] and participation of stakeholders in policy-making is limited [23]. *"Lack of transparency is very pronounced in Lithuania, decisions behind closed doors are a shortcoming that still exists [24]."* The overall responsibility for the supervision of the entire health system rests with the Ministry of Health (MoH). The MoH is strongly involved in formulating health strategies, in drafting legal acts and issuing regulations for the health sector. It also runs health care facilities and public health institutions and has the overall responsibility for health system performance in the fields of individual health care, public health, pharmaceuticals and insurance. A large number of institutions subordinate to the MoH have been established in order to carry out regulatory and governing functions [25]. The most important in the HTA context are the National Health Insurance Fund (NHIF), the State Medicines Control Agency (SMCA), the State Health Care Accreditation Agency (SHAA) and the Institute of Hygiene (IoH). Lithuania has two university hospitals, which play a strong role, one in Vilnius, one in Kaunas [21].

The Lithuanian Health Program 2014-2025 is the main guiding health policy document [26]. Its central goal is to achieve an increase in average life expectancy to 77.5 years by 2025. Evaluation of the previous Lithuanian Health Program 1998-2010 showed an increase of average life expectancy to 73 years and a rapid decrease of infant mortality and of the incidence of tuberculosis.

At the same time mortality from conditions amenable to health care increased in males, as did preventable mortality (deaths that could have been prevented through changes in lifestyle and inter-sectoral measures impacting public health) [25]. Health policy documents approved by Parliament, like the Lithuanian Health Program, stabilize health sector governance in Lithuania, even with changing ministers and governments.

**1990 independence  
2004 EU member**

**relatively poor  
population health  
indicators**

**social health insurance  
system with strong role  
of MoH**

**30% out of pocket,  
mainly for drugs**

**centralized  
health care system**

**National Health  
Insurance Fund NHIF,  
State Medicines Control  
Agency SMCA,  
SHAA State Healthcare  
Accreditation Agency all  
under the MoH**

**2 powerful university  
hospitals:  
Vilnius, Kaunas**

**progress towards  
increase in  
life-expectancy, but  
preventable mortality  
remains a challenge**

**health policy documents  
by Parliament stabilize  
health care system even  
with changing  
governments and  
health ministers**

<sup>1</sup> Latest available figures from 2012, source WHO 2014.

|  |   |
|--|---|
| perceived corruption for inpatient services and in public procurement  | Central and local level public healthcare institutions have constantly appeared among the public institutions perceived as most corrupt in Lithuania [27]. 48% of Lithuanians report having previously paid informally/in cash for healthcare services. Of patients 20% report having paid for outpatient services in the last year and 61% for inpatient (hospital) services [28]. It was projected that the average informal payment per physician visit is EUR 16.– and per hospital admission EUR 80.– in Lithuania [29]. <i>“It depends on the CEO of the individual hospital if patients have to buy their own devices for surgery. Recently there have been 10 scandals in the media. No CEO went to jail, which sends a message to the community [24].”</i> Corruption risks within the healthcare system also concern public procurement, given the rather weak control mechanisms over the procurement process [27]. <i>“There is high corruption in public procurement and pharma [24].”</i> Due to the perceived problem transparency in the public procurement system is constantly increasing. The most transparent are the EU financed projects. |
| EU structural funds – administered by MoH – account for 60% of capital investment in the health system   | EU structural funds have become the main source of capital investment in the health system [20]. In the years 2007-2013 investment financing totaled EUR 57 million p.a., thereof EUR 34 million p.a. from EU funds and EUR 23 million p.a. from the state budget (EUR 6 million p.a. for the 15% co-financing share for EU funds and EUR 17 million p.a. for the state investment program). Funding from the EU will be EUR 27 million p.a. in the period 2014-2020. All healthcare investments on the national level are cleared by a committee appointed by the MoH.   |
| HTA in Lithuania: fragmented<br><br>no independent HTA institution   | Lithuania has little experience with HTA [23]. A systematic application of HTA in Lithuania has been lacking. <i>“HTA today has no influence on procurement [24].”</i> <i>“Decisions are only rarely evidence based.”</i> [24] Prioritization of health resource allocation often reflects a politically driven, rather than evidence-based, decision-making process [20]. <i>“There is an indecisiveness in terms of who is in charge of HTA in Lithuania [24].”</i> HTA activities in Lithuania are fragmented. An independent HTA institution has never been established.  |
| reimbursement of pharmaceuticals follows clear and transparent process ...<br>BUT company pays its own pharmacoeconomic dossier<br>BUT no quality criteria | For an application for NHIF reimbursement of a pharmaceutical (positive list) the submission of a pharmacoeconomic evaluation report to the SMCA has been made mandatory over a decade ago. <i>“A large document needs to be provided by the applying company. There are no quality criteria for such documents [24].”</i> No requirement for this report to be made by an independent institution exists [30]. <i>“Pharmaceutical companies contract pharmacoeconomic evaluations out themselves and provide the contracted experts with their own decision modeling [24].”</i> The application procedure is transparent in terms of what has to be delivered to whom, whereas the ensuing remuneration decision itself is not always. <i>“The process is well structured, if not well developed [24].”</i> A systematic approach to HTA is lacking.   |
| already 3 initiatives to implement HTA:<br>1993 Sweden<br>1999 World Bank<br>presently 2 EU capacity building projects (SHAA, IoH)                         | To address this lack of an integrated HTA process for evidence-based decision-making, Lithuania currently sees what could historically be termed the third effort to establish HTA structures, after initially cooperating in 1993 with the Swedish Council on Health Technology on training of HTA experts and of MoH decision makers and a second initiative in cooperation with the World Bank in 1999 [30]. In 2013 two organizations under the MoH (SHAA, for HTA on medical devices and the IoH, for HTA in public health) gained funding for HTA capacity building from the EU in two separate projects that will run until August 2015. HTA is included in a provision of the current government’s action plan: <i>“Introduce innovative health care technology assessment, deployment and application in order to improve health care efficiency and quality [31].”</i>  |
| HTA mentioned in current government’s action plan  |   |



As a consequence the MoH established an HTA Committee in February 2014 to coordinate HTA activities, to develop a system for the prioritization of health technologies to assess and to examine completed HTA reports and give recommendations to the minister of health based on them. The HTA committee is chaired by a vice-minister. Its membership is comprised of representatives from the MoH, from the NHIF, from the SMCA, from SHAA, from the IoH and from the two university hospitals in Vilnius and Kaunas.

The following chapter describes regulations, actors and decision processes in the Lithuanian health care system in more detail.

### 3.1.2.2 Detailed description of the Lithuanian health care system, decision-makers and regulations

#### Market entry for healthcare services, medicinal products/drugs and medical devices

##### Healthcare service licensing

Healthcare is delivered by public or private healthcare institutions licensed for specific healthcare services. National healthcare institutions are organized and controlled on state and municipal levels. In general, national hospitals are supervised by the MoH, whereas municipalities organise local and regional healthcare.

Three levels of healthcare services exist: primary, secondary and tertiary. Primary level or non-specialized level must be available to all Lithuanian residents and is orientated to the core treatments of patients. Primary level of personal and public healthcare services is organized by each municipality. Secondary and tertiary level healthcare services are in-patient and out-patient care and are provided by healthcare institutions organised by the municipality or the Ministry of Health.

##### *Lithuanian National Health System (LNHS)*

All public and those private healthcare institutions that have concluded annual agreements with territorial branches of the National Health Insurance Fund (NHIF) for compensation of healthcare service costs are statutorily considered to constitute the LNHS. So far over 500 (out of the total of about 2.000) private providers have such contracts. National regulations limit the capacity of institutions which do not belong to the LNHS, i.e. essentially private healthcare institutions without the agreement with territorial branches of NHIF. These are not allowed to provide certain high-level healthcare services. Also, if a non-LNHS institution sends a patient to a LNHS institution such a patient must pay for a visit despite the fact that the patient is insured. Such service costs are however compensated if LNHS institution sends the patient for consultation to other LNHS institution. Non-LNHS institutions claim that this restricts competition and therefore seeks to change the statutory LNHS concept.

**2014: HTA Committee established at MoH to coordinate and develop HTA activities**

**healthcare institutions licenced and controlled by MoH**

**organized on national, regional and local level**

**primary, secondary and tertiary sector**

**public and private healthcare providers**

**private providers restricted**

**healthcare service delivery (professionals and organisations) need licensing**

**MoH responsible for defining requirements**

***Healthcare service licensing requirement***

Healthcare service delivery is a licensed activity. License must be issued before healthcare service can be delivered. Both healthcare professionals and healthcare organisations must<sup>2</sup> be licensed to deliver specific healthcare services. MoH<sup>3</sup> compiles a list of licensed healthcare services and determines<sup>4</sup> licensing requirements for professionals and institutions.

SHAA responsible for applying requirements = accreditation of professionals, services, organisations

requirements for qualifications, capabilities, infrastructure

Healthcare professionals are licensed by the SHAA following the requirements set in orders of the MoH. Separate orders specifying different qualification and experience requirements apply for every healthcare profession. General or specific licensing requirements (e.g. general requirements for secondary level adult chest surgery services<sup>5, 6</sup>) for healthcare institution to engage into certain healthcare service are defined by specific MoH orders. To fulfil general requirements healthcare institution usually must be capable to conduct specific diagnostic or laboratory tests or other specifically mentioned healthcare services, must have certain number of licensed healthcare professionals with specified number of practice years, must have certain medical equipment and/or facilities at the healthcare institution applying for a specific license.

***Healthcare service licensing procedure***

application submitted to SHAA

SHAA must react within 30 days: issue license or refusal

Healthcare organisation licensing process is extensively regulated<sup>7</sup> Applications with appended documents proving that premises, hygienic requirements, staff and their qualification, equipment and other requirements are met are submitted to the SHAA. SHAA adopts a decision to issue the license (within 30 days after the submission of a duly prepared application) or to refuse it. If the application lacks required data, applicant is informed within 20 days following the application day and may be rectified within 90 days. Rectification term suspends the licence issuing term. SHAA informs the applicant about the license refusal within 5 business days following the decision. Following the refusal the applicant may apply repeatedly without any delay.

license is generally indefinite, but can be revoked

Issuance of a license is subject to a state fee. License is indefinite but could be suspended or revoked for a cause prescribed in the Rules of healthcare institution licensing<sup>8</sup>.

***Obligations of a licensed entity***

scheduled and non-planned inspections for quality control

Healthcare service delivery is controlled through scheduled and non-planned inspections. Scheduled inspections follow the plan approved in advance by the SHAA, while non-planned inspection is triggered by complaint relating to the healthcare service quality or upon identification of license infringement

<sup>2</sup> Art. 16 of the Law on Health System

<sup>3</sup> 14 May 2004 order No V-364 of the Ministry of Health

<sup>4</sup> Art. 10(6) of the Law on Healthcare Institutions

<sup>5</sup> Annex No 1 of the 7 November 2000 order No 603 of the Ministry of Health

<sup>6</sup> Item 1.1 of the 30 April 2004 No V-306 of the Ministry of Health

<sup>7</sup> The order is prescribed by the Law on healthcare institutions, the Rules of healthcare institution licensing approved by 2 March 2007 order No V-156 of the Ministry of Health, the List of licensed healthcare services approved by 14 May 2004 order No V-364 of the Ministry of Health and specific Ministry of Health orders laying down licensing requirements for each specific healthcare service

<sup>8</sup> The Rules of healthcare institution licensing approved by 2 March 2007 order No V-156 of the Ministry of Health



by controlling authorities. Supervision of licensed activity takes either of two forms: the request to provide relevant documentation or an on-site inspection. SHAA informs the healthcare institution and the territorial NHIF (if the healthcare institution has concluded a contract with it) about the identified infringement (see also section on Quality Assurance for more details).

Accreditation and certification are both available in Lithuania; however, both are voluntary forms of healthcare quality control and service level development. None of them is required to start or to maintain healthcare service delivery (see also section on Quality Assurance for more details).

**accreditation +  
certification: voluntary**

### Medicinal products/drugs

Medicinal products can be marketed in Lithuania only if registered on national or the EU level or if enrolled into the list of medicine of parallel imported products. The SMCA adopts orders to grant, renew, amend, suspend or withdraw medicinal product marketing authorisation<sup>9</sup> Orders are published on the SMCA website within 3 working days after their adoption.

**only approved drugs  
can be marketed**

**SMCA responsible**

### *Medicinal product marketing authorization requirement*

Product registration follows the Directive 2001/83/EC and other EU standards. Similarly to other EU countries, products need to receive SMCA marketing authorisation (MA) under national, mutual recognition procedure (MRP) or decentralised procedure (DCP) or to possess a centralised European medicines agency (EMA) approval. Parallel importation of both nationally or centrally registered products is also allowed.

**SMCA marketing  
authorization required**

**based on  
MRP or DCP procedure  
or EMA approval**

Registration procedure is chosen according to the type and territorial scope of MA sought:

1. The manufacturer who wishes to obtain marketing authorisation simultaneously in several EEA (European Economic Area) states, including Lithuania, for a medicinal product that has not yet been granted marketing authorisation in any of the EEA states may choose to apply under a *decentralised procedure*. He must supply a dossier identical to that which is submitted to the competent authority/authorities of another state/other states together with the application.
2. The manufacturer who wishes to obtain marketing authorisation of a medicinal product in any EEA state, including Lithuania, other than the state of an existing registration, may choose to apply under a *mutual recognition procedure*. He must supply a dossier identical to that based whereon the medicinal product was granted marketing authorisation by the first state with all the subsequent supplements.
3. The manufacturer who wishes to obtain marketing authorisation of a medicinal product only for Lithuania, and no marketing authorisation has been granted for this product in any other EEA may choose to apply under a *national procedure*.

**decentralised procedure  
(DCP)**

**mutual recognition  
procedure (MRP)**

**but also:  
national procedure**

<sup>9</sup> Medicinal product national registration is primarily governed by the Law on Pharmacy and the Rules on issuing medicinal product marketing authorisation approved by 10 July 2007 order No V-596 of the Ministry of Health

|  |   |
|--|---|
| <p>application includes results of pharmaceutical, pre-clinical and clinical data</p> <p>for original or generic compounds</p>                                   | <p>Along with the application, results of pharmaceutical (physical-chemical, biological or microbiological) pre-clinical (toxicological and pharmaceutical) tests and clinical trials must be submitted. Without prejudice to the protection of industrial property and commercial secrecy, they may be dispensed with if the applicant can demonstrate that the medicinal product is a generic medicinal product of a reference medicinal product which has been authorised for at least 8 years in a EEA state or in the Community (so-called <i>data exclusivity period</i> of the reference medicinal product). Such generic medicinal product may only be supplied to the market after the lapse of not less than 10 years from the day of granting the reference medicinal product initial marketing authorisation (the so-called 2-year <i>market exclusivity period</i> of a reference product). This 10-year exclusivity period may be extended for a maximum of one more year if during the initial 8 years of the said 10 years the marketing authorisation holder registers one or several new therapeutic indications, which according to scientific evaluation performed prior to the clinical benefit compared with the present treatment.</p> <p>Medicinal product marketing authorisation may be granted to a legal person established in any EEA state who is a producer of the medicinal product or who has entered into a contract with the producer setting forth mutual rights and obligations.</p> |
| <p>national MA grant procedure</p> <p>application submitted to SMCA</p> <p>SMCA must react within 20 days, clarifications within 90 days otherwise rejection</p> | <p><b><i>Medicinal product marketing authorization procedure</i></b></p> <p>National MA grant procedure: The standard form<sup>10</sup> medicinal product marketing authorisation application is submitted to the SMCA. Extensive data and documentation including description of GMP compliant manufacturing methods, preclinical and clinical trials, summary of product characteristics, patient information leaflet is appended to the application. SMCA Medicinal product registration division finishes application formalities examination within 20 working days following the submission. Applicant is informed about the application deficiency via email and has to rectify deficiencies within 20 working days following the SMCA request. Failure to do so in time results in application rejection. Application is rejected if requested data is not clarified within 90 days following the SMCA request and product samples should be presented within 20 working days following the SMCA request. Failure to fulfil SMCA request in time results in rejection of the application.</p>   |
| <p>renewal of MA follows same procedure</p>  | <p>To renew medicinal product marketing authorization marketing authorization holder must submit an application<sup>11</sup> to the SMCA. Decision on renewal of documents is adopted within 90 days after submission of application. Application deficiencies are governed in the same order as prescribed for MA applications. Based on pharmacovigilance data sufficiency SMCA decides whether to renew the authorisation and if so whether the MA is indefinite or needs further renewal after 5 years.</p>   |

<sup>10</sup> As approved by the State Medicines Control Agency under the Ministry of Health according to the template provided by the European Commission in Volume 2B of the publication “The rules governing medicinal products in the European Union”

<sup>11</sup> Application form approved by the SMCA according to the template provided by the European Commission in Volume 2C of the publication “The rules governing medicinal products in the European Union” must be supplemented with additional data”

MA variation procedures are conducted under the order prescribed by the Regulation No 1234/2008. Variation is a change to a MA after its grant. A number of variations (ranging from correction of a typo in the patient information leaflet to an addition of a new substance to the product formula) exist. Regulation No 1234/2008 and European Commission guidelines<sup>12</sup> facilitate the classification of variations and prescribe the order to implement the variation.

#### MA variation procedures

The MA of a medicinal product shall be granted or a justified refusal to grant the marketing authorisation shall be given not later than within 210 days from the day of receipt of the properly submitted application. The time of the applicant providing additional documents, information and, as necessary, verbal and/or written explanations required by the SMCA is included in the time of examination of the application.

**altogether no more than 210 days from receipt of submitted application to information on decision made**

#### Medical devices

Medical devices can be marketed in Lithuania only if notified to the SHAA and properly labelled. No registration requirement exists for medical devices. Separate legal acts set regulatory requirements for medical devices<sup>13</sup>, in-vitro medical devices and active implantable medical devices.

**notification to SHAA before marketing required**

#### *Medical device notification requirement*

Before a medical device is put on the market a representative sample must undergo the EC type examination and receive EC type certification from the Notified Body (NB) (private entity approved for certification of medical device sample by the designating authority (SHAA in Lithuania)<sup>14</sup> under the procedure prescribed by the EU<sup>15</sup> and local laws<sup>16</sup>). European Commission administers a list of NB for active implantable medical devices<sup>17</sup>, medical devices<sup>18</sup> and in vitro medical devices<sup>19</sup>. Certification proves that the device sample complies with applicable medical device regulations. Technical com-

**requirement:  
EC certification by NB  
= CE marking**

<sup>12</sup> [http://ec.europa.eu/health/files/betterreg/pharmacos/classification\\_guideline\\_adapted.pdf](http://ec.europa.eu/health/files/betterreg/pharmacos/classification_guideline_adapted.pdf)

<sup>13</sup> Medical norm MN 4:2009 „Technical Regulations on the Safety of Medical Devices“ approved by the Order No V-18 of 19 January 2009 of the Health Minister of the Republic of Lithuania is the main piece of legislation governing the market entry requirements for medical devices.

<sup>14</sup> Item 2.1 of 30 July order No V-732 of the Ministry of Health

<sup>15</sup> Commission implementing regulation (EU) No 920/2013 of 24 September 2013 on the designation and the supervision of notified bodies under Council Directive 90/385/EEC on active implantable medical devices and Council Directive 93/42/EEC on medical devices

<sup>16</sup> Government 4 July 2006 resolution No 674; 30 July order No V-732 of the Ministry of Health

<sup>17</sup> See [http://ec.europa.eu/enterprise/newapproach/nando/index.cfm?fuseaction=directive.notifiedbody&dir\\_id=8&type\\_dir=NO%20CPD&pro\\_id=99999&prc\\_id=99999&ann\\_id=99999&prc\\_anx=99999](http://ec.europa.eu/enterprise/newapproach/nando/index.cfm?fuseaction=directive.notifiedbody&dir_id=8&type_dir=NO%20CPD&pro_id=99999&prc_id=99999&ann_id=99999&prc_anx=99999)

<sup>18</sup> See [http://ec.europa.eu/enterprise/newapproach/nando/index.cfm?fuseaction=directive.notifiedbody&dir\\_id=13&type\\_dir=NO%20CPD&pro\\_id=99999&prc\\_id=99999&ann\\_id=99999&prc\\_anx=99999](http://ec.europa.eu/enterprise/newapproach/nando/index.cfm?fuseaction=directive.notifiedbody&dir_id=13&type_dir=NO%20CPD&pro_id=99999&prc_id=99999&ann_id=99999&prc_anx=99999)

<sup>19</sup> See [http://ec.europa.eu/enterprise/newapproach/nando/index.cfm?fuseaction=directive.notifiedbody&dir\\_id=8&type\\_dir=NO%20CPD&pro\\_id=99999&prc\\_id=99999&ann\\_id=99999&prc\\_anx=99999](http://ec.europa.eu/enterprise/newapproach/nando/index.cfm?fuseaction=directive.notifiedbody&dir_id=8&type_dir=NO%20CPD&pro_id=99999&prc_id=99999&ann_id=99999&prc_anx=99999)

|   |  |
|---|--|
| distinction active implantable medical devices, medical devices and in vitro medical devices    | pliance of each manufactured medical device with the representative sample is approved by the manufacturer following the EC verification procedure and by affixing a CE marking to the product. Once medical device is manufactured, <i>notification</i> requirement and appropriate <i>labelling and usage instructions</i> must be in place to put medical device on the market.   |
| no Lithuanian NB  | No Lithuanian entities are designated to perform NB functions at the moment.   |
|   | <b><i>Notification procedure</i></b>   |
| SHAA must be notified on class IIA, IIB and III devices within 14 days after delivery of device | SHAA must be notified <sup>20</sup> when class IIA, IIB and III and custom made active implantable medical devices are placed on the market. Class I medical devices need no notification. The manufacturer putting the medical device on the market has to notify SHAA within 14 business days following the delivery of the device to the market. Notification is performed in a standard form notice. SHAA registers the device and informs the notifying person within 5 business days from the submission. Labels and usage instructions must be presented along with the notification of class IIa, IIb and III and custom made active implantable medical devices.  |
| standard form submission  |  |
| electronic equipment: registration in Registry of Manufacturers and Importers                   | If the medical device is a piece of electric or electronic equipment, in addition to the notification procedure the supplier (either manufacturer or distributor representing it) must register with the Registry of Manufacturers and Importers. This registration must be done before the device is put on the market. This registration incurs certain waste management obligations <sup>21</sup> .   |
| also notification on changes of device to SHAA  | SHAA must also be informed about any change in notified data. Such notification must be submitted within 14 business days following the change of data by the person who made initial notification.  |
|   | <b><i>Labelling and usage instructions</i></b>   |
| detailed requirements for the usage instructions  | Each medical device must have information to ensure its safe use. Such information is provided on the label and instructions for use. All medical devices, other than devices which are custom-made or intended for clinical investigations, must bear a CE mark accompanied by the identification number of the NB responsible. Instructions for use must be included in the packaging for every medical device, except devices of class I or II a, if they can be used safely without any such instructions. Detailed requirements for the usage instructions and labels correspond to those specified in the Annex 1 of Directive 93/42/EEC concerning General Medical Devices. All medical devices falling in to the category of electric or electronic equipment must also be labelled accordingly. |

<sup>20</sup> Notification procedure is governed by the are established by the Rules on Submission of Information about IIA, IIB, III Class and Custom Made Active Implantable Medical Devices approved by the Order No V-938 of 16 November 2009 of the Ministry of Health

<sup>21</sup> Obligations are governed by Art. 34<sup>1</sup> of the Law on Waste Management and the Rules on Registration of Manufacturers and Importers approved by the Order No D1-291 of 27 May 2009 of the Ministry of Environment Protection

## Investment in healthcare

Public healthcare service providers have very limited funds to invest. Savings from the services provided are usually used for routine maintenance, whereas state and municipal budgets and the EU structural assistance (including assistance from Switzerland and EEA Grants) are the main sources for capital investment to healthcare in Lithuania.

**very limited Lithuanian funds for investments**

**State investment and EU funds**

### State Investment Programme

On the national level State Investment Programme (the **Programme**) plays a major role as capital investment for public healthcare institutions (both owned by the state and by municipalities). The Programme is approved by the Government for at least 3 years period<sup>22</sup>. Each governmental authority or institution is setting programme priorities for their governance domain<sup>23</sup>. Investments in health care are governed by the MoH. New priorities for investments in health care were established in 2013<sup>24</sup>:

**capital investment for public healthcare institutions**

**priorities governed by MoH**

1. Mother and child health improvement;
2. Disease prevention and control assurance;
3. Decreasing morbidity and mortality from non-communicable diseases;
4. Renovation of institutions infrastructure.

**priority areas: primary and secondary prevention, infrastructure**

Closely following these priorities healthcare institutions develop investment projects. Application to include the investment project in the State Investment Programme should be submitted to the MoH. The investment projects selection committee, appointed by the MoH, selects projects for funding. Project planning, financing, implementation and control procedures are described in the MoH order No V-1081<sup>25</sup>.

**healthcare institutions submit investment applications to MoH**

**MoH selection committee**

Projects are selected according to selection criteria, healthcare institution performance indicators and policy principles. For the 2013/15 investment period the following policy principles were approved<sup>26</sup>:

**selection criteria, performance indicators and policy principles 2013-15:**

1. to focus on funding low number but high impact investment projects, in order to complete at least several projects and to allocate more funds to ongoing projects which have already achieved at least half of the required funding and to fast-track them;
2. to intensify funding for projects executed by healthcare institutions which are prospective in terms of economic and medical indicators and which are expected to aggregate regional patient flows;
3. to account the proportion of total funds allocated for a specific project to date;
4. to finance projects challenging problems of particular relevance: updating sterilization units, replacing obsolete lifts, eradicating emergency condition and so forth.
5. since 2013 to fund projects of particular importance only, ones strengthening healthcare institution and increasing its regional importance.

**a few projects with high impact**

**completion of ongoing projects**

**impact on patient flows**

**urgency, relevance, importance**

<sup>22</sup> Art. 14 of the Law on Investments

<sup>23</sup> The rules for governance of the capital investments from the state budget approved by the April 2001 resolution No 478 of the Government.

<sup>24</sup> Approved by the April 2013 order No V-346 of the Ministry of Health.

<sup>25</sup> Approved by the December 2010 order No V-1081 of the Ministry of Health.

<sup>26</sup> Approved by the January 2013 order No V-20 of the Ministry of Health.

|  |   |
|--|---|
| <p><b>concrete selection criteria:</b></p> <p><b>ongoing projects up to 300,000.- for completion</b></p> <p><b>solution to urgent problem</b></p> <p><b>EU- or municipal co-financed</b></p> <p><b>quality management</b></p> <p><b>reduce in-patient, optimize out-patient services</b></p> | <p>Selection criteria for investment projects are annually revised and approved by the MoH. Currently the following criteria<sup>27</sup> are in force:</p> <ol style="list-style-type: none"> <li>1. ongoing investment project which requires up to EUR 300,000 for completion;</li> <li>2. the investment project is intended to solve urgent problematic cases, when supporting documents are presented;</li> <li>3. investment project is co-financed with the assistance of EU structural or other international funds;</li> <li>4. investment project co-financed from municipal budget and/or institution funds;</li> <li>5. continuing investment project;</li> <li>6. investment project, when institution has implemented quality management system(s);</li> <li>7. Investment projects on specialized out-patient, emergency care, day-care, day-surgery and observation services development, intended to minimize in-patient services.</li> <li>8. municipality contributes own funds for preventive activities</li> <li>9. new investment project, which starts and ends during the current budget year and cost up to EUR 100,000.</li> </ol> |
| <p><b>EU funding 2007-2013 for MoH programs: almost EUR 300 million</b></p>  | <p><b>Investments from EU funding and co-financing</b></p> <p>Total allocation of EU structural assistance for Lithuania in all policy sectors for the period 2007-2013 (from the European Social Fund, European Regional Development Fund and Cohesion fund) amounts to more than EUR 6.775 billion (EUR 7.423 billion – including national co-financing). This almost equals an additional annual Lithuanian state budget. EU structural assistance allocated to operational programs administered by the MoH amounts to almost EUR 300 million (including national co-financing) for that period.</p>  |
| <p><b>Lithuanian Strategy for the use of European Union Structural Assistance: human resource development, economic growth, promotion of cohesion etc.</b></p>   | <p>EU structural assistance for Lithuania for the period 2007-2013 will be allocated in accordance with the national general strategy: the Lithuanian Strategy for the use of European Union Structural Assistance for 2007-2013 (approved the European Commission on the 26<sup>th</sup> of April, 2007) and with 4 operational programs for implementation of this strategy<sup>28</sup>:</p> <ol style="list-style-type: none"> <li>1. Operational Programme for the Development of Human Resources for 2007–2013;</li> <li>2. Operational programme for the Economic Growth for 2007–2013;</li> <li>3. Operational Programme for Promotion of Cohesion for 2007–2013;</li> <li>4. Technical assistance Operational Programme for 2007–2013.</li> </ol>  |

<sup>27</sup> Approved by the April 2013 order No V-346 of the Ministry of Health.

<sup>28</sup> Approved by the April 2007 in the European Commission

In accordance with the operational policy area, the MoH is responsible for the implementation of the first objective “To provide high quality and affordable health care services” of the second priority “Quality and accessibility of public services: infrastructure of health care, social care and education” of the Operational Programme for Promotion of Cohesion for 2007-2013. Twelve measures were defined by the Government to achieve this objective (see Table 3.1-2)<sup>29</sup>.

**MoH is responsible for 1 objective: “provision of high quality and affordable health care services” as task in “Promotion of Cohesion”**

*Table 3.1-2: Funds allocated and contracted for Operational Programmes under MoH administration for the year 2007 to 2013 (including EU Funds and national co-financing funds)*

| No           | Measure   | Number of projects | Funds allocated EUR million | Contracts signed EUR million |
|--------------|---|--------------------|-----------------------------|------------------------------|
| 1            | Decreasing morbidity and mortality from cardiovascular diseases (National)  | 1                  | 45.318                      | 45.318                       |
| 2            | Updating infrastructure of health care institutions providing emergency services in case of injuries and other external causes (National)       | 16                 | 50.155                      | 50.882                       |
| 3            | Updating infrastructure of ambulances and urgent consultation providers (National)  | 1                  | 7.233                       | 7.899                        |
| 4            | Early diagnostics of oncological diseases and full-fledged treatment (National)   | 10                 | 49.184                      | 49.145                       |
| 5            | Establishment of differentiated complex psychiatric centres for child and family (National)   | 5                  | 3.038                       | 3.199                        |
| 6            | Modernization of Psychiatric in-patient care (National)   | 8                  | 4.024                       | 4.181                        |
| 7            | Modernization of infrastructure for mental health service surveillance (National)   | 1                  | 0.189                       | 0.189                        |
| 8            | Establishment of psychiatric day hospitals (centres) (Regional)   | 27                 | 9.820                       | 10.055                       |
| 9            | Establishment of crisis intervention centres (Regional)   | 5                  | 2.436                       | 2.437                        |
| 10           | Development of outpatient, palliative and nursing services and optimization of inpatient services (National)                                    | 109                | 99.990                      | 101.038                      |
| 11           | Development of Public health care infrastructure in municipalities (Regional)   | 27                 | 4.011                       | 4.063                        |
| 12           | Infrastructural investments for provision of public outpatient and inpatient services delivered by private health care institutions (Open call) | 37                 | 5.011                       | 5.008                        |
| <b>Total</b> |   | <b>247</b>         | <b>280.409</b>              | <b>283.414</b>               |

*Source: EU structural assistance information management and supervision system<sup>30</sup>.*

All projects financed from the EU Structural Funds for the period 2007-2013 must be completed by the end of September 2015. By the May 2015, 91 % (EUR 255.308 million) of contracted EU funding has been absorbed.

**all EU Structural Funds projects Sept. 2015 completed**

<sup>29</sup> Approved by the July 2008 resolution No 787 of the Government.

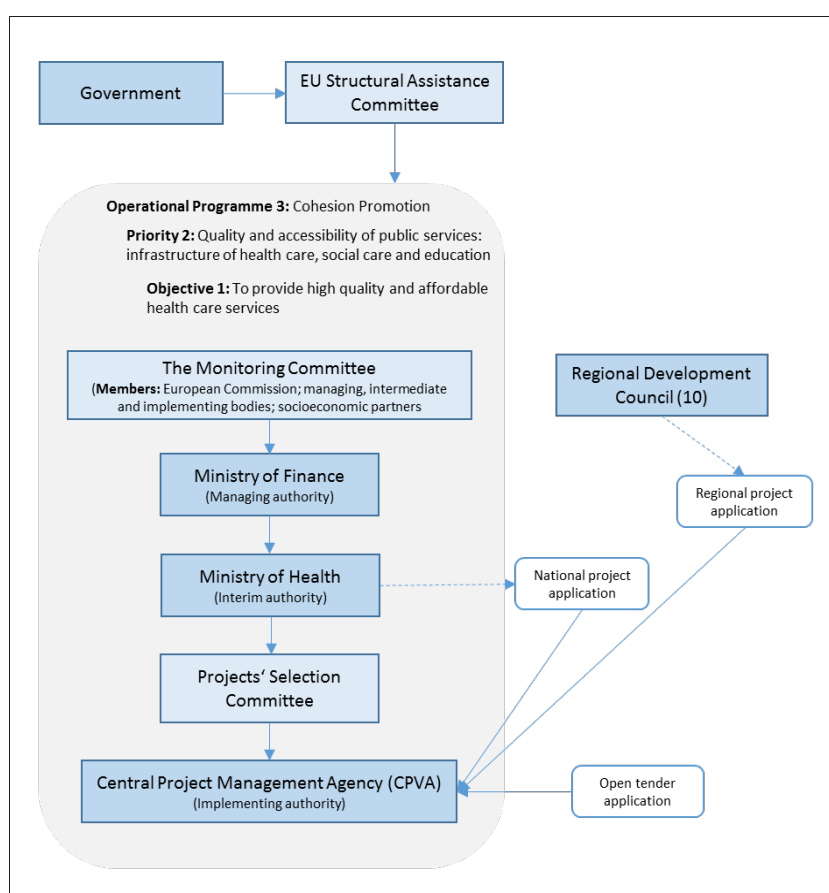
<sup>30</sup> Ministry of Finance. Information updated on the 30 of January 2012 according to the data from EU structural assistance information management and supervision system Retrieved on the 15 of May, 2015.



***EU funded projects administration process for the period 2007-2013***

**MoH as an interim  
authority administers  
8 measures**

EU funded projects are administered and financed in accordance to the rules established by the Government<sup>31</sup>. There are three different types of EU funded projects: national, regional and open tenders. National and regional projects are planned by compiling and approving national and regional projects' lists. National level projects are planned by ministries and (or) other state institutions, whereas 10 Regional Development Councils are responsible for planning of the regional projects. The MoH as an interim authority administers 8 measures covered by the national selection. National projects are planned in accordance with National projects' planning procedure of the MoH<sup>32</sup>.



*Figure 3.1-1: Administration of EU Funds (2007-2013)*

**EU funding for  
2014-2020  
for all policy areas  
EUR 8,386 billion**

Key national strategic documents for the implementation of the EU Cohesion policy are the Partnership Agreement and the Operational Programme for EU Structural Funds Investments for 2014-2020 approved by the European Commission in 2014. The Lithuanian multi-fund Operational Programme brings together 5 EU investment funds with total allocated budget of EUR 8,386 billion.

<sup>31</sup> The rules for administration and finance of EU projects approved by the December 2007 resolution No 1443 of the Government.

<sup>32</sup> Approved by the April 2008 order No V-299 of the Ministry of Health (updates: September 2011, No V-834; June 2012, No V-648).



The Operational Programme is based on National Progress Programme for 2014–2020<sup>33</sup> which aims to implement provisions of the EU strategy “Europe 2020” and Lithuania’s progress strategy “Lithuania 2030”. Ministry of Finance is the managing authority of the EU funding for 2014-2020 and the MoH is assigned to administer two objectives of the priority No 8 “Social inclusion and poverty reduction”:

- ✿ to improve quality and access to health care for the target populations and to reduce health inequalities (European Regional Development Fund (ERDF));
- ✿ to decrease health inequalities by improving quality and accessibility of health care for the target populations and by promoting healthy aging (European Social Fund (ESF)).

The MoH has allocated EU structural investment funds to implement aims, objectives and measures in individual health development priority areas (see Table 3.1-3)<sup>34</sup>.

**MoH is responsible for 2 objectives on “Social inclusion and poverty reduction”:**

**improve quality and access and to reduce health inequalities,**

**decrease health inequalities by improving quality and and by promoting healthy aging**

*Table 3.1-3: Planned Budgets from EU Structural Funds for Operational Programmes under MoH administration for the year 2014 to 2020*

| o                               | Priority area  | Planned budget from<br>EU structural funds for 2014-2020 |                                |                               |
|---------------------------------|--|--|--------------------------------|-------------------------------|
|                                 |  | Total<br>EUR<br>mio                                      | Incl.<br>ERDF funds<br>EUR mio | Incl.<br>ESF funds<br>EUR mio |
| 1. Reducing health inequalities |  |  |                                |                               |
| 1.1.                            | Increasing effectiveness of tuberculosis prophylaxis, diagnosis and treatment  | 17.4   | 11.3                           | 6.1                           |
| 1.2.                            | Improving access to prevention, treatment and social reintegration services for people addicted to alcohol and other psychoactive substances | 7.0  | 5.1                            | 1.8                           |
| 1.3.                            | Improving access to effective health care for persons with disabilities  | 11.0   | 9.6                            | 1.4                           |
| 1.4.                            | Decreasing morbidity and premature mortality from diseases of circulatory system   | 20.9   | 16.2                           | 4.6                           |
| 1.5.                            | Decreasing morbidity and premature mortality from cerebrovascular diseases   | 42.0   | 36.2                           | 5.8                           |
| 1.6.                            | Preventing injury and decreasing disability and mortality from external causes   | 14.5   | 8.1                            | 6.4                           |
| 1.7.                            | Assuring of oncological diseases prevention and effective treatment  | 22.3   | 17.4                           | 4.9                           |
| 1.8.                            | Assuring health promotion, disease prevention and effective treatment for children   | 46.3   | 36.8                           | 9.6                           |
| Total                           |  | 181.3  | 140.7                          | 40.6                          |
| 2. Healthy aging                |  |  |                                |                               |
| 2.1.                            | Developing of health promotion and other preventive health services  | 16,0   | 11,6                           | 4,4                           |
| 2.2.                            | Falls prevention   | 1.4  | –                              | 1.4                           |
| 2.3.                            | Improving mental health  | 3.5  | –                              | 3.5                           |
| 2.4.                            | Establishing health promoting conditions at work   | 3.5  | 2.3                            | 1.2                           |
| 2.5.                            | Organizing network for combined nursing and geriatric care provision   | 12.2   | 11.0                           | 1.2                           |
| 2.6.                            | Preventing inflammatory and degenerative rheumatic diseases and diseases caused disability   | 2.9  | 2.3                            | 0.6                           |
| Total                           |  | 39.4   | 27.2                           | 12.2                          |

<sup>33</sup> Approved by the November 2012 resolution No 1482 of the Government.

<sup>34</sup> Approved by the July 2014 order No V-795 of the Ministry of Health.

**rules for the  
administration of  
EU-funds 2014-2020:  
ev. similar**

Although rules for the administration and financing of EU structural investment projects for 2014-2020 have not been approved yet, it is likely to be similar to ones of the 2007-2013 funding period.

### Investments on Large Scale Medical Devices

**approval from the  
MoH needed for large  
devices from list or costs  
> EUR 145,000**

All public healthcare institutions are required to obtain the approval from the MoH when purchasing large scale medical devices (from the list approved)<sup>35</sup>, or when estimated acquisition price (value added tax included) of the device including accessories is greater than EUR 145,000.

**SHAA collects data  
on medical devices  
> EUR 29,000**

The SHAA collects data on large scale medical devices, costing over EUR 29,000, or those bringing an annual revenue from the NHIF to providers of more than EUR 290,000. The information collected includes financial and usage intensity indicators for public providers; private providers not contracted by the NHIF only report starting and final dates of the usage of the equipment<sup>36, 37</sup>. In the table below, SHAA information on the use of large scale medical devices is presented.

*Table 3.1-4: Large scale medical devices operated in 2013 and newly acquired in 2014 by the public and private health care institutions in Lithuania*

| Device   | In use in 2013 | Newly acquired in 2014* | Total |
|--|----------------|-------------------------|-------|
| Computed tomography (computed tomography X-ray equipment)            | 68             | 1                       | 69    |
| Magnetic resonance tomography (magnetic resonance imaging equipment) | 33             | 0                       | 33    |
| Mammograph (mammographic X-ray equipment)                            | 37             | 0                       | 37    |
| Ultrasound device  | 684            | 36                      | 720   |
| Angiography (a specialized X-ray angiography equipment)              | 26             | 0                       | 26    |
| Gamma camera (gamma ray camera)                                      | 9              | 0                       | 9     |
| Linear (electron/photon) accelerator                                 | 11             | 0                       | 11    |
| Diagnostic X-ray equipment   | 396            | 7                       | 403   |
| Positron emission tomography (PET)                                   | 1              | 1                       | 2     |

\* data presented from public health care institutions only

Source: SHAA

**2010/12 EUR 51.8 million  
for large devices**

In 2010/12 EUR 51.8 million from the State Investment Programme (including EUR 47.5 million EU and co-financing funding and EUR 4.3 million State budget funding) were spent on the acquisition of large scale medical devices, which accounts for 25 per cent of the total health care investment programme<sup>38</sup>. The applications are considered in the Coordination committee for large medical devices<sup>39</sup>. The members of the committee are personally appointed by the MoH. The committee decisions are based on formal criteria<sup>40</sup>.

<sup>35</sup> Approved by the October 2012 order No V-947 of the Ministry of Health.

<sup>36</sup> Approved by the May 2010 order No V-383 of the Ministry of Health.

<sup>37</sup> Approved by the March 2011 order No T1-224 of the head of SHAA.

<sup>38</sup> According to the Operational Audit Report: How diagnostic procedures with Large Scale Medical Equipment are organized?/Approved by November 2013 of the National Audit Office of Lithuania.

Internet <https://www.vkontrole.lt/failas.aspx?id=3086> [retrieved on 19/05/2013].

<sup>39</sup> Approved by the June 2013 order No V-585 of the Ministry of Health.

<sup>40</sup> Approved by the May 2013 order No V-457 of the Ministry of Health.

- ✿ Demand meets the provision of strategy papers;
- ✿ Number of particular devices in Lithuania is not higher than EU average;
- ✿ Current/planned workload of particular device is not lower than the national average;
- ✿ Planned services meets evidence based needs;
- ✿ A qualified health care personnel is provided;
- ✿ Particular devices are geographically equally distributed;
- ✿ Operational life of the concurrent medical device exceeds recommendations.

**formal criteria for decisions:**

**demand-provision**

**EU-average**

**average utilization**

**geographic distribution**

## Funding and reimbursement of healthcare services, medicinal products/drugs and medical devices

### Healthcare funding

Most of health services are publicly funded (national or municipal budgets based on compulsory health insurance funds (CHIF)), but for certain services also privately funded (direct patient payments, private health insurance) health care provision exists. Despite being advocated by the private sector, the private health insurance is still at the early stage and with the coverage of about 1% of population is of limited significance to the system at large.

**mostly publicly funded**

**private sector covers only 1% of population**

CHIF is the main source for funding public healthcare and is comprised of public health insurance instalments paid by all economically active residents (around 40% of total CHIF income) as well as of state insurance contributions (about 60% of total CHIF income) on behalf of the rest of the population, mainly socially vulnerable groups.

**compulsory health insurance**

Different funding schemes exist. Primary care is based on capitation payment. Additional payments for certain services (e.g. home visits to newborns, cervical cancer screening, etc.) and for exceptional services are available. Secondary and tertiary services rely both in inpatient and outpatient care basically on per case payments from CHIF. About 70% of CHIF is used for these purposes. The rest is divided among reimbursement of medicines (around 17%), medical rehabilitation, centrally purchased medicines and preventive health programmes.

**different funding schemes:**

**capitation per case payments**

### Healthcare cost compensation practice

Healthcare activities for the LNHS are compensated via a complex system of allocating “points” (each point has a base price, but not always a fixed value) to services. Compensation is calculated by multiplying the numbers of services delivered with the acquired “points”. The sum is transferred through the territorial branches of NHIF. A contract sum is negotiated with the healthcare institutions prospectively in the beginning of the year and is generally based on the historical service demand (figures from previous years). The amount that is actually transferred to the institution is determined by multiplying the actual base price with the total number of healthcare service points. But the contracted sum cannot in any way be exceeded.

**complex system of prospective calculations and retrospective compensation via “points” allocated to healthcare services**

|  |  |
|--|--|
| <p><b>intention:</b></p> <p><b>neither to intervene in determination of number of services nor to let the costs explode by maximizing number of services</b></p> | <p>Healthcare institutions are free to individually determine the amount of services that they will deliver over the year. Outperforming, i.e. delivering more services than the amount set in the contract reduces the value of the base price. Healthcare institutions are however precluded from deciding to lower the amount of service delivery because the maximum value of base price is capped at a standard rate. This complicated compensation mechanism allows to manage public healthcare spending when the actual service demand cannot be controlled. As a result of this compensation system, the increase in patient flows does not increase the total healthcare costs of the institution (neither it increases the revenue).</p> |
| <p><b>balancing between demand and CHIF income</b></p>   | <p>In principle, base price calculations are a financial solution for balancing the rising demand for healthcare services and the limited income of CHIF resources.</p>  |

### Procurement models in the public sector

Public sector institutions (hospitals) use the following main models to procure pharmaceuticals:

|   |  |
|---|--|
| <p><b>Central Procurement Organisation for some drugs</b></p> | <p>✳ Certain drugs are procured through the Central Procurement Organisation (CPO). This allows public institutions to avoid complicated public procurement procedures. Instead, they only publish relevant information about certain drug on the CPO public catalogue. CPO organises the competition among all potential suppliers on the lowest price basis. Public institution then must enter into procurement contract with the winner;</p> |
| <p><b>or</b></p>  |  |
| <p><b>hospital tenders</b></p>                                | <p>✳ Other drugs are procured through hospital tenders;</p>  |
| <p><b>or</b></p>  |  |
| <p><b>centralized CHIF tenders</b></p>                        | <p>✳ Expensive patented medicines (e.g. antiretroviral drugs, some cancer therapies) are procured by CHIF through centralised tenders. As of 2013 CHIF has changed the way patented medicines with a single provider are procured. Patented medicines amount to 80-95% of total expenditure on centralized tenders and because of the single provider cost-containment is hard to achieve.</p>   |

|   |   |
|---|---|
| <p><b>suboptimal: different prices for different institutions</b></p> | <p>The remaining problem with CPO and public procurements is that in some instances the price for the same product differs up to several times for different hospitals.</p> |
|---|---|

### Pricing of drugs

|   |   |
|---|---|
| <p><b>2010: statutory pricing for drugs led to decrease of prices</b></p> | <p>In 2010 statutory pricing was introduced to all non-reimbursable pharmaceuticals and decreased the price level by about 10%. As a result of certain price containment measures, in 2010 CHIF expenditure on reimbursement pharmaceuticals fell for the first time since 2002. Pricing schemes for reimbursable and non-reimbursable pharmaceuticals vary, however maximum mark-ups apply for both. This preserves the competition among the respective distribution chain players.</p> |
|---|---|

|   |   |
|---|---|
| <p><b>also non-reimbursable and OTC products are price-regulated:</b></p> | <p>Marketing Authorization Holders (MAH) must declare prices for each of the non-reimbursable prescription and OTC products to the MoH. With minor exceptions, failure to do so prohibits the sale of such product to the general public. Prices are regulated by setting maximum wholesale and retail mark-ups for such products. Distributors and pharmacies take the declared price for granted and freely apply mark-up within the set limits which range up to 18% and up to 30% (depending on the declared price) for wholesalers and retailers respectively.</p> |
| <p><b>reimbursable and non-reimbursable pharmaceuticals:</b></p>          |   |

Pricing of reimbursable products within the distribution chain is similar to that of non-reimbursable products. Manufacturer's price should not exceed the declared price while the wholesale and retail prices for retailers and the patient respectively are calculated by adding statutorily set maximum wholesale and retail mark-ups of up to 14% and up to 22% respectively (depending on the purchase price).

**maximum wholesale and retail prices by MoH prescribed**

### Main measures for cost-containment for drugs

The following main measures for optimisation of CHIF spending apply for reimbursable pharma products:

- ✱ Grouping products with different active substance but interchangeable therapeutic action for the basic price
- ✱ "Price tunnel" for generics;
- ✱ "Price tunnel" for products entering the group with products of the same active substance from more than 3 manufacturers;
- ✱ "Price tunnel" for new products entering the group that had first generic entry in 2004-2009;
- ✱ Requirement for new packaging entering the group with products of the single manufacturer to be cheaper;
- ✱ Reimbursing composite products according to the component with lowest price;
- ✱ Price negotiations are started with the supplier when the declared price exceeds 95% of reference country average. Portfolio and other trade-offs are acceptable but very rare;
- ✱ Cost-volume agreements may be voluntary or mandatory. The latter are concluded with the manufacturer in specific saturations (e.g. when all the products within the therapeutic group belong to the single manufacturer; when the product required more than 1% of CHIF or EUR 290,000 for reimbursement last year). These agreements oblige the supplier to return the amounts exceeding certain agreed cap.

**regulatory instruments:**

**group pricing  
price tunnelling  
negotiations  
cost-volume agreements  
cost-caps**

### Reimbursement procedures for drugs

Only prescription drugs are reimbursed. New applications for reimbursement are only successful for products with high pharma-economic and therapeutic value calculated in comparison with the closest alternatives. The Pharmaceutical Reimbursement Commission performs this assessment and delivers its non-binding decision to the Compulsory Health Insurance Council for further scrutiny. Compulsory Health Insurance Council and the NHIF both deliver separate reimbursement recommendations and the MoH adopts the final decision. Applications are submitted to and scrutinized by the Pharmacy department of the MoH which also calculates the base price and highest retail prices for products. Products are enrolled into the reimbursable pricelists with the MoH order.

**positive list for products with high pharma-economic and therapeutic value = reimbursable drugs**

**recommendations by 2 drugs-commissions  
MoH final decision**

Every medicinal product reimbursement application must include a pharmaco-economic analysis prepared according to the Recommendations adopted by the MoH.<sup>41</sup> The Recommendation is based on a classic cost-benefit assessment of product efficacy and safety data and treatment costs, compared and contracted against the closest therapeutic alternative. The main methodology

**drug reimbursement application must include a pharmaco-economic analysis**

<sup>41</sup> 20 January 2003 order No V-26 of the MoH

|   |  |
|---|--|
|   | <p>principles suggested for the assessment include: the analysis should be country-specific; analysis must focus on healthcare and economic comparison; assessment should be performed for approved dosages and indications; specific pharmaco-economic methods must be used; reliability of results must be critically evaluated; cost comparison for the achievement of treatment result must be performed; selected assessment methods must be reasoned.</p>  |
| <p>reimbursable product<br/>pricelist published<br/>1 x p.a.,<br/>but (irregular)<br/>supplements more often</p>  | <p>The reimbursable product pricelist is issued once a year with pricelist supplements appearing irregularly several times a year. Periodicity for issuing pricelist supplements is not statutorily set and varies depending on a number of successful reimbursement applications. Due to the rules encouraging price competition among reimbursable products with the issuance of each pricelist supplement the base price for particular product group may change or certain product may even drop off the list. Irregular issuance of pricelist supplements reduces revenue predictability for reimbursable product providers.</p>  |
| <p>budget impact is<br/>relevant for decisions<br/>for positive list<br/>a “reserve list” consists<br/>of potential candidates<br/>for the positive list,<br/>depending on budget</p> | <p>The impact on the budget is also considered when adopting positive reimbursement decision. If when compared with the closest alternatives the product (already with sufficient pharma-economic and therapeutic value) requires additional budgetary funds it falls within the reserve list. The list includes products that could be reimbursed when required funding becomes available. Currently, the regulations are vague on what particular conditions these reserve products could be moved from the reserve list into reimbursable product list and introduce some uncertainty for reserve list product providers.</p>   |
| <p>reference pricing</p>  | <p>Along with the decision to reimburse the MoH approves the base price and the highest retail price. Base price is calculated according to specific formula which includes the average of reference country price (international reference pricing).</p>  |
| <p>generics:<br/>“price tunnel” model</p>   | <p>Reimbursement of generics follows the so-called “price tunnel” model. To be reimbursed the first generic must offer a price which is no less than 50% lower than the innovative alternative to be included into the reimbursable list. The second and the third generic to enter the list must further lower the price so that it does not exceed 85% of the cheapest product in the group and should not exceed 95% of the reference price average. Each further generic entrant decreases the price even more. “Price tunnel” for biosimilars is even more rigid.</p>   |
| <p>lower prices the more<br/>generics come to<br/>the market</p>  |  |
| <p>different reimbursement<br/>rates for drugs and<br/>patient co-payment:<br/>100%, 90%,<br/>80% or 50%</p>  | <p>Currently, 100%, 90%, 80%, 50% (of a base price) reimbursement rates apply, thus leaving the rest of the sum for the patient co-payment. All reimbursable products except insulin have patient co-payment. The industry often draws attention that the consumption of products with 50% reimbursement rate is relatively low allegedly due to the high co-payment. Manufacturer aiming for higher sales can offer discounts for patient co-payment under a strictly regulated procedure. Discount cannot be offered in any other way.</p>   |
| <p>positive list also for<br/>medical devices:<br/>C-List</p>   | <p><b>Reimbursement and pricing of medical devices</b></p> <p>Reimbursement of medical devices (medical aid devices) is organized under same system as medicinal products. The MoH has approved a list of conditions for which medical treatment would be compensated from the national budget. Base and the highest retail prices of reimbursable medical devices are approved only for those medical devices that have been listed in the List of Diseases and Reimbursable Medical Devices for their Treatment (so called C-List) approved by the MoH, and in respect whereof an application has been received for including them in the Price-List of Reimbursable Medicinal Products.</p> |

The LNHS reimburses only the base price of the medicinal product and only certain compensation level of such base price (100%, 90%, 80% or 50%). The base price is calculated under the certain formula and in principle is a certain part of the lowest retail price of the medicinal product within a certain group of products. Accordingly, patients buying a reimbursable medicinal product have to make a co-payment for it.

**different reimbursement rates for devices and patient co-payment: 100%, 90%, 80% or 50%**

In general, the selling price of medicinal product in the whole distribution chain is not statutory fixed in Lithuania. Wholesale and retail prices are set by the wholesalers (distributors) of the medical devices and the retailers (pharmacies) respectively. However, a certain highest price thresholds which cannot be exceeded while selling medical devices in the distribution chain (wholesaler, retailer or final customer/patient) are statutorily set. The MoH approves the base, the highest retail prices and the highest wholesale and retail mark-ups of reimbursable medical devices, and the highest wholesale and retail mark-ups of non-reimbursable medical devices.

**MoH sets maximum prices for wholesalers and retailers**

## Quality assurance

### Healthcare service delivery quality assurance: external quality control

External healthcare quality assurance system consists of:

- a. healthcare institution licensing and control of licensed activity;
- b. healthcare institution accreditation;
- c. healthcare institution certification.

The following subjects (the **Control institutions**) are entitled to perform healthcare service control:<sup>42</sup>

**control of licensed activity**

1. Persons appointed by the MoH (when needed);
2. SHAA is the main institution controlling healthcare service access, quality and economic efficiency;
3. NHIF performs economic control of public funds (amount and quality) spend on healthcare services;
4. Lithuanian medicine ethics committee performs control of healthcare service ethics;
5. Public Health Centres under the MOH control public health services access, quality and economic efficacy in the regions of Lithuania and as a rule also have representations in every municipality.

**carried out by different institutions on and different levels**

Control institutions are entitled to:<sup>43</sup>

**control instruments and consequences**

1. Enter into the healthcare institution premises;
2. Get required documentation, laboratory tests, patient data, to interview staff for the purpose of the inspection;
3. Require additional tests to be performed on patients;
4. Request the MoH to withdraw the licence for a healthcare professional or for the healthcare institution;
5. Require that certain healthcare professionals be removed from their duties for 1 months to check their professional competences;

<sup>42</sup> Art. 52 of the Law on Healthcare Institutions

<sup>43</sup> Art. 53 of the Law on Healthcare Institutions



6. Apply sanctions (to warn the institution and to order the rectification of the deficiencies; to impose administrative sanctions; to request to check professional competences of the healthcare professionals, to suspend all or part of services, to temporally dismiss the managerial bodies of the institutions)<sup>44</sup>.

**SHAA supervises inspections and controls in a scheduled or non-planned manner**

Healthcare professionals and healthcare institutions are both controlled by SHAA. This is a mandatory supervision whether statutory licensing conditions are obeyed throughout the healthcare delivery. SHAA inspections might be scheduled and non-planned. Scheduled inspections<sup>45</sup> target medical device manufacturers, representatives, importers, distributors and users (healthcare institutions using medical devices) as well as healthcare services providers (healthcare institutions). Non-planned inspection<sup>46</sup> of is performed for different causes: the request from the MoH, a complaint that the service quality in particular healthcare institution does not meet the prescribed standard, inspection whether the deficiencies identified during previous inspection were duly rectified; etc. Scheduled and unplanned inspections are free of state fee.

**SHAA: annual inpatient service level indicator survey**

SHAA performs and publishes annual inpatient healthcare institutions service level indicator survey. This survey aims to inform patients about the service level in certain institutions. Service level indicators (e.g. patient satisfaction, antibiotic resistant microbes monitoring level) are approved by the MoH<sup>47</sup>. The 2014 indicator survey is available on the Internet.

**voluntary accreditation for healthcare institutions by SHAA**

Healthcare institutions may voluntary elect to be accredited by the SHAA<sup>48</sup>. Accreditation is a voluntary initiated evaluation aimed to determine whether healthcare institution meets specific set of quality standards.<sup>49</sup> So far healthcare accreditation programme is developed only for the primary out-patient healthcare institutions in Lithuania.<sup>50</sup> These standards were developed as a result of EU structural fund project. Accreditation standards are prepared by academic institutions in cooperation with healthcare professional association.<sup>51</sup> Compared to licensing, accreditation has some advantages. First, no pressure of sanctions; second, maximum achievable standards are set for accreditation to encourage healthcare institution for continuous development (licensing standards are mere safety ensuring minimal mandatory standards).

**until now no accreditations were performed  
healthcare institution certification**

So far no accreditations have been performed in Lithuania.

Certification is a voluntary initiation of healthcare institution assessment according to particular standards (e.g. ISO 9000 standards) and formal recognition that these standards are met. Authorised authority which is usually a private entity performs certification.

There is no objective public data gathered to verify the number of certified national healthcare institutions.

<sup>44</sup> Art. 58 of the Law on Healthcare Institutions

<sup>45</sup> Scheduled inspection order is governed by 3 May 2011 order No T1-390 adopted by the head of the SHAA

<sup>46</sup> Unplanned inspection order is governed by 6 February 2013 order No T1-136 adopted by the head of SHAA

<sup>47</sup> 28 November 2012 order No V-1073 of the Ministry of Health

<sup>48</sup> Art. 6 of the Law on Healthcare Institutions

<sup>49</sup> Art. 11 of the Law on Healthcare Institutions

<sup>50</sup> Standard available at:

[http://www.SHAA.gov.lt/files/Istaigu\\_licencijavimas/Standartas%20LT\\_visas.pdf](http://www.SHAA.gov.lt/files/Istaigu_licencijavimas/Standartas%20LT_visas.pdf)

<sup>51</sup> Art. 6(7) of the Law on Healthcare Institutions



## Healthcare service delivery quality assurance: Internal audits of healthcare institutions

Minimal healthcare quality requirements are approved by the MoH<sup>52</sup> and cover the following sets of service requirements: patient safety, diagnostic and treatment methods and protocols, sound internal audit activities, healthcare service quality management and development. Internal healthcare institution audit schemes implement and follow these basic MoH approved rules. Also, these principles serve as the guidelines for healthcare institution's independent service quality development.

Internal audit is organised by:<sup>53</sup>

1. Manager of the healthcare institution in an institution of up to 5 healthcare professionals;
2. Appointed employee or outsourced, if the institution holds 5-50 healthcare professionals;
3. Internal medical audit group formed under the order of the healthcare institution manager, if the institution holds 50-300 healthcare professionals;
4. Internal medical audit department established in the institution holding more than 300 healthcare professionals.

Internal audit functions are the following:<sup>54</sup>

1. To engage in determining the healthcare service quality policy, aims and quality indicators;
2. To prepare internal audit procedure;
3. To deliver annual internal audit report to the manager of the healthcare institution and to the department managers;
4. To perform scheduled and non-planned audits under the direction from the manager of the healthcare institution;
5. To compile an audit plan according to the managers directions;
6. To organise the registration of side effects and their analyses;
7. To monitor patient satisfaction within the institution;
8. To examine patient claims to the extent this falls within its competence;
9. If assigned by the manager of the healthcare institution, to represent the institution towards the Control institutions;
10. To participate in developing internal documentation related to the development of healthcare service quality;
11. To analyse healthcare service quality improvement.

The manager of each healthcare institution approves separate internal audit procedures: They are not publicly available. Proper documenting of side reactions related to the use of medicinal products, medical devices, blood components, hospital infections, x-ray incidents, side effects related to delivery and transplant of cells, tissues and organs is regulated by the MoH.<sup>55</sup>

**audit schemes follow minimal quality requirements set by the MoH**

**organised by management, audit department or appointed groups**

**for many reasons:**

**investigation into hospital acquired infections**

**complaints from patients**

**wishes for quality improvement**

**documentation of adverse events of drugs and devices is regulated by MoH**

<sup>52</sup> 29 April 2008 order No V-338 of the Ministry of Health

<sup>53</sup> Item 13 of the 29 April 2008 order No V-338 of the Ministry of Health

<sup>54</sup> Item 16 of the 29 April 2008 order No V-338 of the Ministry of Health

<sup>55</sup> 6 May 2010 order No V-401 of the Ministry of Health

**SHAA is responsible to oversee medical device safety, market delivery and usage**

**control through market data, vigilance data documentation and inspections**

**managers responsible for appropriate use of medical devices**

**documentation of critical incidents (registries) data documentation on usage**

### Medical device quality assurance

SHAA is competent<sup>56</sup> to oversee the medical device market from the perspective of device safety, market delivery and usage. Medical device manufacturers, distributors and importers are subject to the main market delivery requirements control (labelling, etc.). Also, SHAA controls how healthcare institutions obey the rules on medical device instalment, usage and maintenance.<sup>57</sup>

Medical device market control is performed by SHAA through the:

1. Reception of market data about medical devices used;
2. Documentation of vigilance data delivered by manufacturer or service provider on medical devices;
3. Application of market safeguard measures (to order withdrawal of medical devices from the market, to suspend of to prohibit market entry).<sup>58</sup>
4. Schedules and non-planned inspections on market players.

Managers of healthcare institutions are responsible to ensure that medical devices are used according to the conditions set by the manufacturer in the healthcare institution.<sup>59</sup> Manager must appoint a person responsible for the following activities in the healthcare institution:<sup>60</sup>

1. To record medical device incidents<sup>61</sup> and to report them to the SHAA;
2. To manage a registry of all medical devices that need electric power;
3. To deliver certain data (i.e. characteristics, utility hours per month, number of procedures performed with such a device per months, purchase price, usage costs per months) about the usage of large scale medical devices in the healthcare institution.

### Medicinal product quality assurance

**SMCA is responsible to oversee licensing, drug safety, standards in production**

**control through documentation of pharmacovigilance information**

Medicinal product quality is ensured through:

1. Licensing regimes;
2. Regulatory standards (good practices) for each sector of medicinal product distribution chain (pre-clinical investigations; clinical trials; manufacturing; distribution; retail sale through pharmacy stores or in-patient healthcare institutions; medicinal product pharmacovigilance reporting);
3. Scheduled and non-planned SMCA inspections in each part of medicinal product distribution chain.

Manufacturers, distributors and retail pharmacies undergo periodic scheduled inspections and non-planned SMCA inspections. Depending on the type of activity performed by the inspected entity, SMCA may issue good manufacturing practice certificate, good distribution practice certificate or good pharmacy practice certificate. Failure to eliminate licensing activity infringements

<sup>56</sup> Art. 75(2)(5) of the Law on Health System;

<sup>57</sup> 3 May 2010 order No V-383 of the Ministry of Health

<sup>58</sup> Items 61-64 of the 19 January 2009 order No V-18 of the Ministry of Health

<sup>59</sup> Item 11 of the 3 May 2010 order No V-383 of the Ministry of Health

<sup>60</sup> Item 12, 13, 48, 49 of the 3 May 2010 order No V-383 of the Ministry of Health

<sup>61</sup> Defined as a medical device malfunctioning event that could have resulted or can result in death or severe injury of the patient

identified during the inspection may lead to a temporal suspension or withdrawal of respective license. Pharmaceutical activity is illegal without a valid license.

If regulatory requirements are infringed with respect to the medicinal product (e.g. inappropriate labelling, product safety issues) MA may be suspended or withdrawn.

## Existing HTA infra-structure

Private and public healthcare institutions as well as institutions engaging in public (societal) health services (e.g. preventive health programmes) are obliged to use health interventions (technologies) which are approved for use in Lithuania<sup>62</sup>. It is prohibited to use personal healthcare and public health interventions (technologies) except for instances prescribed by law<sup>63</sup>. The MoH is obliged<sup>64</sup> to set the order for Health Technology Assessment (HTA).

However, this is a mere legal principle with little further elaboration in law and in practice so far.

HTA institutional structure consists of the HTA Committee (the Committee) and institutions performing the HTA (the SHAA, the SMCA and the IoH) (the HTA subjects).

The Committee, established by the MoH in 2014<sup>65</sup>, coordinates and develops HTA implementation and application. The Committee is thus a coordinating body and does not have direct HTA activities among its functions. Subject performing the actual HTA are the SHAA, the SMCA and the Hygiene Institute each in its dedicated field. Both the SHAA and the Hygiene Institute has so far acquired the EU structural funds for HTA development projects (2013-2015). Therefore, preparation of HTA procedures is done or under way in these institutions. Also, each of these institutions has published information about 3-5 HTAs concluded so far. The SMCA has publicly announced about its engagement to HTA activities (through EUnetHTA), however, no further accomplishments seems to have been achieved so far. So far, HTA activities seem to develop individually within HTA subjects and overall coordination is minimal.

The Committee activities are governed by the Rules of procedure and the Committee Statute.<sup>66</sup> Both acts are abstract and very procedural in nature. No substantive provisions (e.g. how the Committee interacts with HTA subjects, what are the Committees policy priorities) are included. These legal acts are not published so far. MoH intend to do so soon.

**inspections**

**sanctions**

**overall HTA structure:  
legal foundation for  
HTA is written down**

**legal principle is not  
filled with life yet**

**HTA Committee  
established 2014 in MoH**

**wants to coordinate and  
develop HTA  
implementation and  
application**

**individual HTA-doer  
with minimal  
coordination:  
SHAA  
SMCA  
IoH**

**HTA-Committee based  
on Rules of procedure  
and on the Statute**

**... under development**

<sup>62</sup> Art. 45(1)(4) and 50(1)(3) the Law on Healthcare Institutions

<sup>63</sup> Art. 54(1) of the Law on Health System

<sup>64</sup> Art. 54(2) of the Law on Health System

<sup>65</sup> Established by the 21 February 2014 order No V-277 of the Ministry of Health

<sup>66</sup> Both approved by the same 21 February 2014 order No V-277 of the Ministry of Health

|   |   |
|---|---|
| <p><b>functions of HTA-Committee:</b></p> <p>determination of techs to be assessed</p> <p>priority setting</p> <p>development of HTA agenda</p> <p>coordination of int. activities</p> <p>awareness</p> | <p>The Committee performs the following functions<sup>67</sup>:</p> <ol style="list-style-type: none"> <li>1. along with HTA subjects determines healthcare technologies that should be assessed and delivers a list of such technologies for the MoH;</li> <li>2. approves HTA priorities specified by HTA subjects;</li> <li>3. examines HTA reports and recommendations delivered by HTA subjects and provides its own recommendation to the Minister of Health;</li> <li>4. coordinates HTA subject activities;</li> <li>5. along with HTA subjects sets HTA development agenda;</li> <li>6. coordinates international HTA initiatives;</li> <li>7. engages in HTA awareness raising.</li> </ol>                        |
| <p><b>institutions are members of the HTA-Committee, not the HTA-units within the institutions</b></p>  | <p>Although HTA subjects are referred to as institutions (not designated HTA bodies within those institutions or their members) in the Committee Statute or Rules of Procedure, in practice the Committee coordinates HTA activities within the HTA subjects (e.g. the Commission within the SHAA or respective SHAA officials knowledgeable of HTA and appointed to the Commission). Committee rights are limited to invitation of external consultants and request additional information to perform its functions. Rules of procedure state that any data provided to the Committee is confidential. As a consequence, HTA reports are not available for peer reviewing and public use. HTA transparency is lacking.</p> |
| <p><b>Committee handles confidential information</b></p>  |   |
| <p><b>MoH assigns chairperson and its members</b></p>   | <p>The MoH assigns Committee the chairperson and its members. Rules of procedure govern the composition of the Committee. It reserves an undefined number of seats for the MoH, single seat remains with every HTA subject and two major medical universities in the Committee. However, the composition may be expanded with representatives of other institutions or agencies. Currently, the Committee consist of 19 persons (12 of them are from MoH and only 3 represent academia).</p>  |
| <p><b>MoH has undefined number of seats, others 1 seat each per institution</b></p>   |   |
| <p><b>now 12 MoH members, 7 others</b></p>  | <p>The Committee members are appointed by the MoH and are the following<sup>68</sup>:</p>   |

Table 3.1-5: Members of the HTA-Committee established in 2014

|    | Institution | Function   |
|----|-------------|--|
| 1  | MoH         | Chairperson<br>Vice Minister                                 |
| 2  | MoH         | Deputy chairperson<br>Advisor to the MoH                     |
| 3  | MoH         | Head of EU Support section                                   |
| 4  | MoH         | Chancellor   |
| 5  | MoH         | Director of Mother and Child Health Agency                   |
| 6  | MoH         | Head of Health Economics Department                          |
| 7  | MoH         | Head of Health Care Accessibility and Acceptability Unit     |
| 8  | MoH         | Director Pharmacy Department                                 |
| 9  | MoH         | Director LNHS Coordination and Healthcare Institution Agency |
| 10 | MoH         | Head of Legal Department                                     |

<sup>67</sup> Item 7 of the Statute approved by 21 February 2014 order No V-277 of the Ministry of Health

<sup>68</sup> 8 January 2015 order No V-277 of the Ministry of Health

|    | Institution          | Function   |
|----|----------------------|--|
| 11 | MoH                  | Director Health Strengthening Agency   |
| 12 | MoH                  | Head of Health Strategic Development section   |
| 13 | SMCA                 | Director of SMCA   |
| 14 | SHAA                 | Head of Medicine Technology Division   |
| 15 | NHIF                 | Head of Clinical coding section  |
| 16 | Institute of Hygiene | Public Health Technology Center/Head of Research and Technology Assessment Unit  |
| 17 | University Kaunas    | Lithuanian University of Health Sciences<br>Director for Public Health, Research and Education   |
| 18 | University Kaunas    | Kaunas Clinics Hospital, Department of Innovation Assessment and Deployment<br>Lithuanian Health Sciences University, Faculty of Public Health |
| 19 | Vilnius University   | Professor Medicine faculty   |

According to the Statute Committee members are entitled to:

1. suggest Committee agenda;
2. examine documentation;
3. deliver suggestions to the Committee;
4. voice opinion during the Committee hearings;
5. vote.

**members:**  
suggest agenda,  
examine documentation  
etc.

Committee chairperson:

1. calls Committee hearings (no further regulation is set as the regularity of the hearings, the chairperson seems to be absolutely free when and whether to set up a hearing date);
2. manages the Committee;
3. leads Committee hearings.

**chairperson:**  
calls hearings

Committee decisions are adopted following majority vote with chairperson's vote being decisive when other votes are equally split. Members may vote via email.

**majority vote**  
**chairperson's vote**  
**has special weight**

No regulation is set as to the further use of Committee decision. According to unofficial statements from the MoH officials, the Committee decisions are provided to the Minister for information and reference only. The ultimate decision relating to the health interventions (technologies) is adopted by the Minister. Allegedly, this set up intends to ensure the separation of consultation body (the Committee) and public administration powers (the Minister).

**HTA-Committee**  
**recommendations for**  
**decision support to**  
**minister,**  
**not binding**

### Medical device and related technology HTA

HTA is theoretically mandatory<sup>69</sup> – but not applied in everyday practice – for medical devices and related technologies (medical devices and related methods, methodologies, procedures and interventions used by healthcare professionals for healthcare service delivery) in situations when:

1. The cost of medical device related technologies is over 29.000 EUR (100.000 LTL);
2. The medical device related technology is intended to be fully or partially acquired from public funds (state or municipal budget, etc.);

**appraisal-decision-**  
**making separate**

**HTA for medical devices**  
**is mandatory in theory,**  
**if**

**cost of medical device**  
**is > 29 000 EUR**  
**acquisition with**  
**public funds**

<sup>69</sup> Item 2 of 12 February 2013 order No T1-165 of the head of SHAA

|   |  |
|---|--|
| within priority area:<br><br>expensive,<br>equally effective,<br>significant effects<br>expected,<br>vulnerable patient<br>group,<br>etc. | <ol style="list-style-type: none"> <li>3. The medical device related technology falls within the following priority technologies for HTA assessment: <ol style="list-style-type: none"> <li>3.1. Expensive or new/innovative modification of a current technology;</li> <li>3.2. Technology equally effective to a current alternative on the market;</li> <li>3.3. Technology capable of significantly reducing sickness rates;</li> <li>3.4. Technology capable of being applied to a wide patient scope;</li> <li>3.5. Technology applicable to a dependant patient group;</li> <li>3.6. Technologies related to implantable medical devices;</li> <li>3.7. Technology related to detecting, controlling, treating and restoring health disorders.</li> </ol> </li> </ol>   |
| SHAA is responsible for HTA on medical devices  | SHAA has set the Order for medical device related technology HTA (the Order). <sup>70</sup> The Order governs merely procedural aspects of Commission's activities and includes no other matters. To initiate a HTA private entities aiming to sell such technologies must fill in standard form application and attach additional studies or HTA analysis performed on the technology in other countries. Having received the application, SHAA perform formal examination of the application within 7 days following the submission and allow (if needed) 30 day period for the applicant to rectify identified formal deficiencies. If no formal deficiencies are found, SHAA assigns the application to the earliest hearing of The Evaluation Commission for Health Technologies Related to Medical Devices (the Commission). The Commission, established back in 2012 by the SHAA, gathers at SHAA premises and includes SHAA officials and outside academic and patient organisation experts. The Commission decides whether particular application falls within the priority and, if so, assigns SHAA to perform HTA evaluation and present its recommendation within 90 days. Indeed currently SHAA has no priority medical device technologies approved. All HTA applications are evaluated in chronological order. SHAA is currently waiting until the MoH approves priority technologies for HTA. No public information is available as to what the priority list could include. |
| formal submission files from manufacturer/distributor incl. HTA-information   |  |
| Evaluation Commission in SHAA set up in 2012  |  |
| SHAA is assigned to make HTA in 90 days   |  |
| future: priority setting by MoH   |  |
| after HTA Commission compiles recommendation and informs MoH and applicant  | The term may be prolonged by 30 days if SHAA finds that additional documentation is needed. HTA report conducted is delivered to SHAA for review. The Commission compiles recommendations based on the HTA report and delivers these recommendations to the MoH and to the applicant. The Order does not specify whether the HTA report is confidential and remains only for further reference of the SHAA or has to be published. SHAA publicly presents only the abstract of the HTA report. The Commission takes a central role in the HTA process related to medical devices, at least in theory. It drives medical device HTA policy, directly engages in execution of HTA, and prepares interventions (technology) use and purchase recommendations.   |
| Commission has central role (presently only in theory)  |  |
| 12 representatives Commission meetings: theoretically 2-3x p.a., in practice not at all in recent times                                   | The Commission consists of 12 persons appointed by the head of SHAA. 8 members represent medical associations, the rest are representatives of SHAA. Commission activities are governed by the Rules of procedure. <sup>71</sup> The Commission hearing is held upon initiation of the SHAA but no less frequent than every half a year. In practice the Commission has not met for a long time. Commission members and the SHAA can both form the agenda for the Commission hearing. Chairperson of the Commission may invite outside experts to contribute to the Commission hearings.   |

<sup>70</sup> 12 February 2013 order No T1-165 of the head of SHAA

<sup>71</sup> 13 December 2012 order No T1-1541 of the head of SHAA

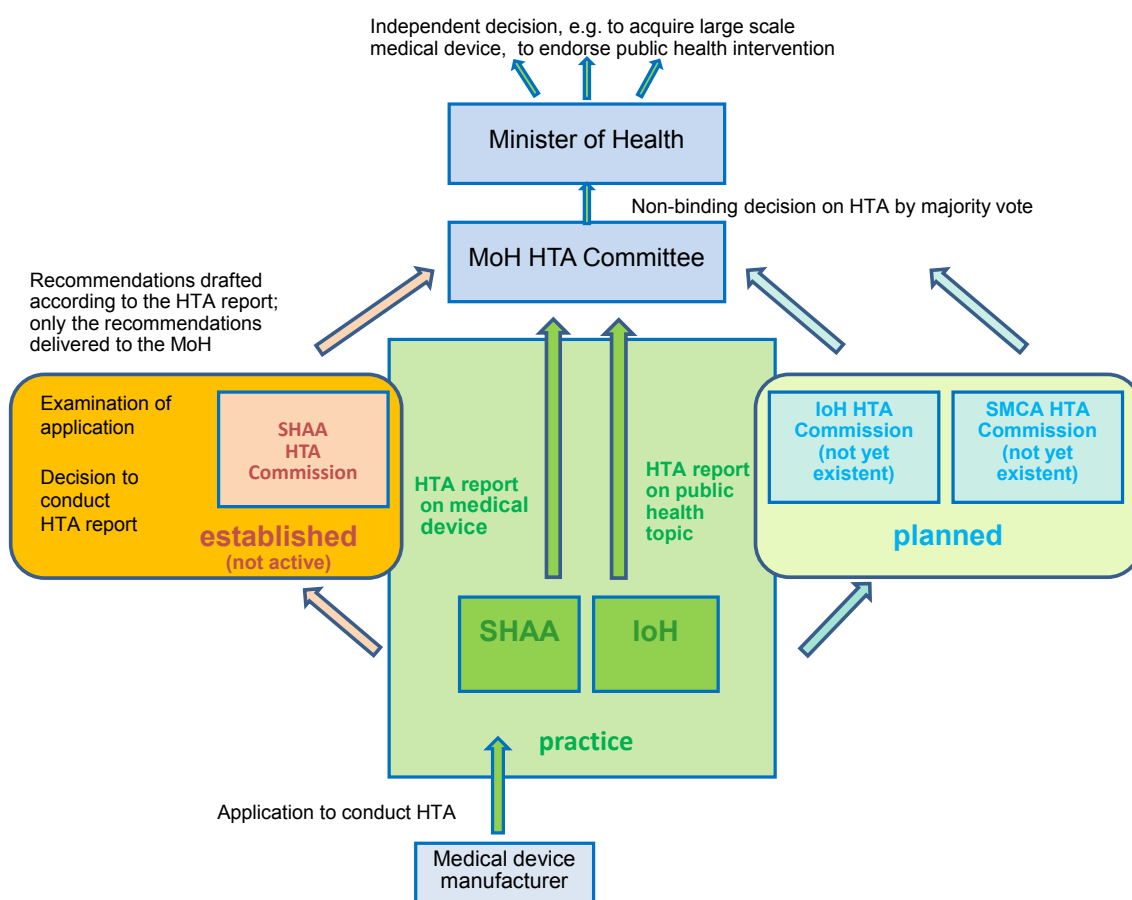


Figure 3.1-2: HTA infrastructure flowchart

### Public health service HTA

The Institute of Hygiene is in charge of building and developing HTA for Public Health interventions. A Research and Technology Unit exists in both Public Health Technology Centre (division of the Institute of Hygiene) and in the Profession Health Centre (another division of the Institute of Hygiene). These units engage in HTAs according to their field competence. A regulation on the procedures for HTA for Public Health interventions has not been adopted yet, but is under development. The rules and procedures will likely be analogous to the Order adopted by SHAA. The IoH forecasts this for September 2015. HTA for Public Health interventions is supposed to deliver comprehensive and scientifically proven data on effective interventions to health policy makers and healthcare professionals. The IoH has already performed 3 HTAs, of which 2 reports are published.

**IoH responsible for HTA for public health interventions**

**rules and procedures in development**

**3 HTAs performed**

### HTA on Medicinal products/drugs

SMCA is in charge of building and developing HTA for medicinal products. Last year SMCA acceded to the EUnetHTA network. A regulation on the procedures for HTA for drugs has not been adopted yet. SMCA will likely adopt the rules and procedures under its order. The rules and procedures will likely be analogous to the Order adopted by SHAA. No public information is available on HTA performed (if any) on drug-interventions.

**SMCA responsible for HTA for drugs**

**early stage  
no HTA performed yet**



## 3.2 Analysis of utilization of HTA in health care and barriers

### 3.2.1 International examples for HTA utilization and applications, but also barriers

**HTA for wide range of decision-makers**

Technology assessments are useful to a wide range of decision-makers in health care, including government policy makers, insurance companies and other payers, planners, administrators, clinicians, patients and industry.

**along the whole life cycle of technologies**

In a life cycle of health technologies HTA plays a role at different points in time and with different methodological approaches.

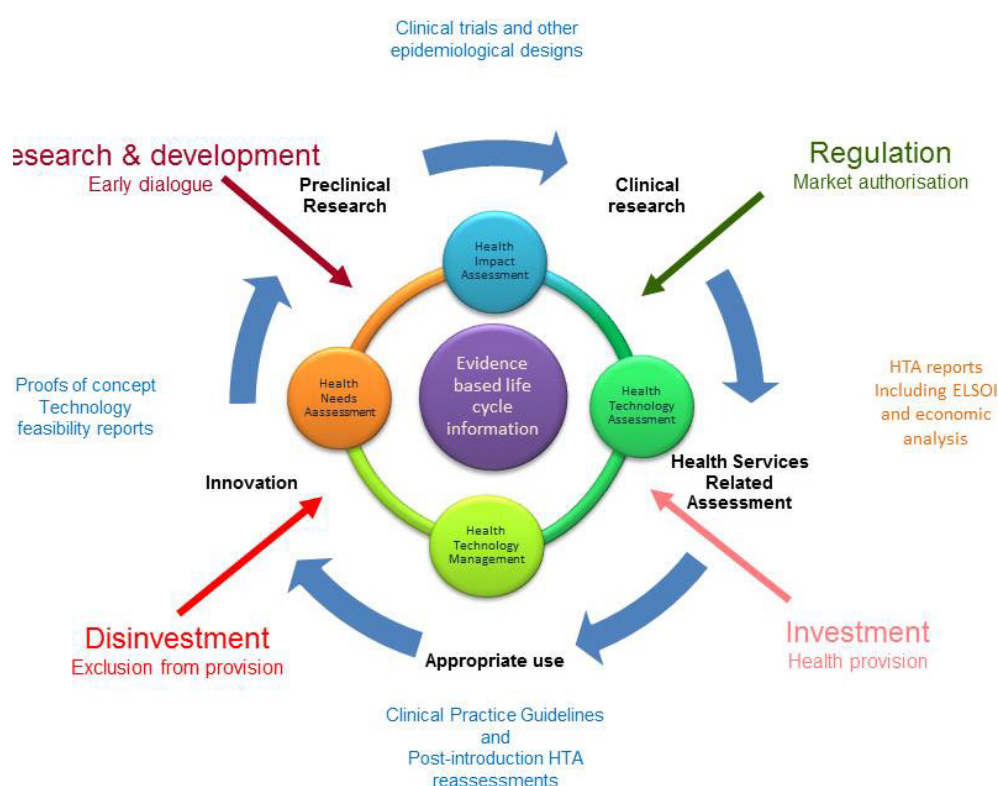


Figure 3.2-1: The life cycle of health technologies [32]

**prevalent utilizations:**

The actual utilization of HTA for evidence-informed health policy decisions is stimulated by the information need and the according demand of decision-makers for tailor-made timely HTA-products. The following HTA utilizations are prevalent:

**in-/exclude new interventions**

*Decisions to in-/exclude new interventions (drugs, procedures, devices) in benefit catalogues or positive/negative lists: single technology assessments (STA) are most often the methodology of choice.*

**benefit catalogues or positive lists**

*Decisions to in-/exclude new interventions (drugs, procedures, devices) in benefit catalogues or positive/negative lists: relative effectiveness assessments (REA) give the basis for either deciding in favour of one technology or for negotiating (in cases of equal benefit-risks) group prices.*



*Decisions on Disinvestment* of obsolete or unsafe interventions or such of uncertain benefit (e.g. in the process of the maintenance of the benefit-catalogue or positive list): clinicians are often involved for the identification of candidates for disinvestment, followed by STAs or REAs.

**disinvestment**

*Decisions on procurement of new technologies* (e.g. in hospitals, drug or implant commissions): available technologies are listed and categorized in groups of technologies. Then group assessments are carried out, with special focus on add-on services of manufacturer (technical maintenance, training, timely delivery etc.).

**procurement**

*Decisions on planning and placement of big devices (e.g. PET) or specialized services (e.g. neurosurgery)*: HTA for planning and placement is based on Health Care Needs Assessment (HCNA) incorporating conventional approaches (prevalence and incidence data) with quality and outcome data.

**planning  
and placement**

*Decisions on quality improvement*: HTA gives input to clinical pathways and evidence-based (care) guidelines and/or inputs to quality (patient relevant outcome) indicators but also to a quality-quantity relations (e.g. in high-risk elective surgery).

**quality improvement**

*Decisions on appropriateness* (e.g. in cases of high amount of regional variances but equal health outcomes of population): HTA gives input to definition of patient groups according to patient characteristics, severity of disease, natural course of disease, threshold values.

**appropriateness**

*Decisions on controlled diffusion and coverage with evidence development* (e.g. if a technology is “promising” but not proven or if the benefit of an intervention is uncertain, but the demand/pressure from providers or patients is high): HTA supports the generation of (“pragmatic”) evidence under research conditions with inputs to registries and clinical trials (e.g. the definition patient-relevant of outcomes, instruments to measure them, etc.).

**controlled diffusion**

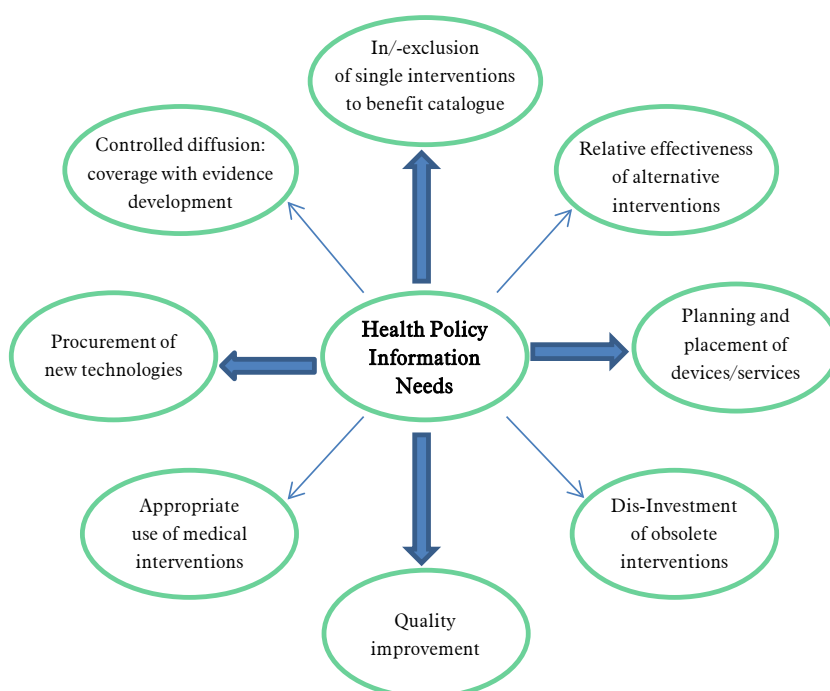


Figure 3.2-2: Common utilizations (need and demand) of HTA

## Barriers and hindrances in the utilization of HTA

**barriers:**  
**timing,**  
**access to HTA**  
**poor dissemination**  
**resistance of**  
**professional bodies and**  
**lack of managerial will**

The gap between HTA research and medical practice or health policy is often considered as a problem [33]. The timely access to good quality (reliable, valid, clear in messages) and relevant HTAs is perceived as a barrier. Other barriers are organisational factors such as poor dissemination of HTA, lack of material and personnel resources (skills of politicians to understand the need and opportunities of evidence and skills of HTA-staff to understand the needs and priorities of politicians), staff turnover, but also resistance of professional (clinical) bodies or managerial will for a change in the decision-making culture (from “eminence to evidence”).

**facilitators:**  
**relationships,**  
**trust and respect**  
**understanding of**  
**political needs**

Strategies to increase the use of research evidence are good contacts, collaborations and permanent relationships with health politicians and administrators, but also trust and mutual respect for each other professional needs. To increase the utilization and impact of HTA a good understanding of the processes, the context and competing priorities as well as the political pressure is of advantage [33].

### 3.2.2 Analysis of perceived need within the Lithuanian health system, and barriers

#### Needs assessment based on interviews

*“It is better to have a[n HTA] system than to have no system. One can then improve an existing system and build capacity [24].”*

**demand for rational**  
**system of making**  
**decisions with an HTA**  
**component**

The need for a rational system of decision-making on investment and reimbursement was apparent to interviewed experts. *“Decisions on investments above a certain threshold need to be evidence-based [24].”* The need for an HTA-function within it was also obvious: *“The establishment of HTA as an obligatory part of informed decision-making is desirable [24].”*

#### *HTA needs at MoH and NHIF*

**MoH and NHIF need**  
**to know about**  
**where and when**  
**to invest**  
**how to address me-too**  
**medical devices**  
**appropriateness for**  
**Lithuania**  
**disinvestment**

Decision support is needed in deciding where to allocate limited financial resources both at the MoH and at the NHIF, which, in addition, needs to determine at what stage of the life-cycle of a technology to reimburse. *“Ideally the first step would be to make an HTA [24].”* The market for medical devices was cited as an example of many similar products with unclear respective advantages and unclear value for money for the funder. An expectation voiced is to learn from an HTA if the technology is appropriate for Lithuania, for whom it should specifically be provided and if Lithuania can afford to pay for it: *“A different kind of analysis than seen in the two HTAs presented at the [MoH HTA Committee] so far [24].”* Arguments based on clinical effectiveness and evidence-based economic arguments are required also to justify decisions not to invest and for removing ineffective items from reimbursement lists to make financial room for effective innovations.

**HTAs on public health**  
**to inform**  
**implementation of**  
**EU programs**

Decision support is also required when it comes to determining with which measures to best implement strategies and programs. The MoH for example needs decision support for implementing the EU funding program 2014-2020, with its special focus on public health and investment in evidence-based practice. Figure 3.2-3 highlights Lithuania’s present primary HTA needs.

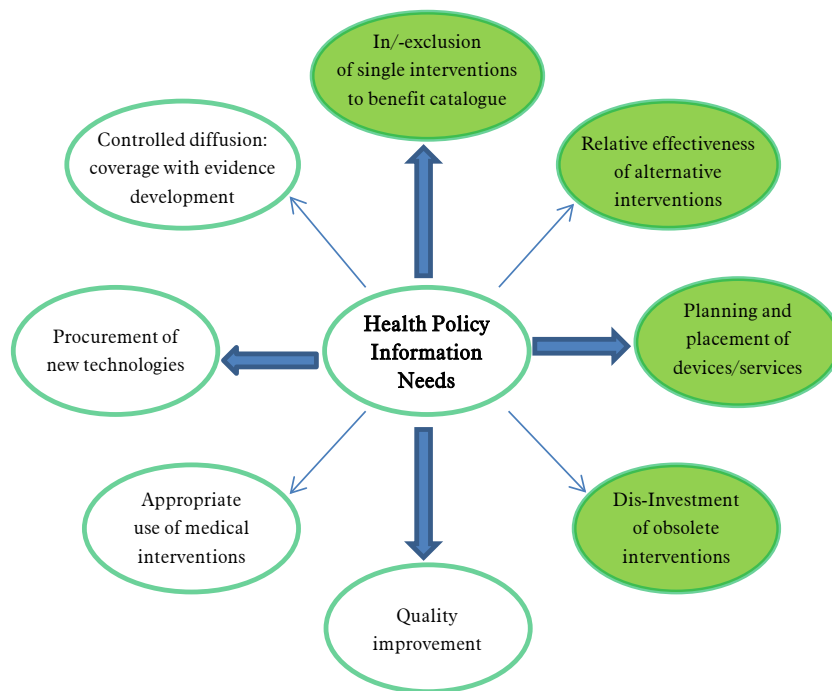


Figure 3.2-3: Primary HTA needs in Lithuania

### Perceived barriers based on interviews

When it came to the narrower HTA process, “an indecisiveness about who is in charge of HTA in Lithuania [24]” was observed. The importance of putting an HTA system in place became very clear from the expert interviews. “National HTA should function according to a clear playbook [24].” The independence of HTA is widely recognized as a defining feature of an HTA process. Interviewed experts called for the depoliticization of the current HTA regime and the addressing of existing conflicts of interest of HTA doers that result from their direct or indirect contacts to policy makers. It was noted that companies applying for the reimbursement of a drug should not be the ones commissioning evaluations/HTA of the drug themselves, as is presently the case. An HTA function was seen to conflict with a regulatory function if both were located at the same institution.

A body prioritizing HTAs needed for Lithuania was seen as necessary. In addition to reviewing applications for HTAs from university hospitals, other providers of health care and from manufacturers, prioritizing should also encompass a proactive approach of looking ahead at which health technologies would become relevant for the Lithuanian health care system (horizon scanning). In addition prioritizing of HTAs should include existing technologies, whose effectiveness is in doubt, as candidates for future disinvestment.

dependence on politics and industry, most urgently pharma

politicization of present regime

conflict between regulatory and HTA functions within one organization

call for:

proactive prioritizing of HTA topics incl. horizon scanning

|   |  |
|---|--|
| <b>coordination of HTA demand and supply</b>          | Coordination is seen as vital on the demand side for HTAs (MoH, NHIF, SMCA, SHAA) as well as among doers of HTA (presently SHAA and IoH). HTA doers should cooperate on HTAs with broader topics. The desired HTA process should include a clear system of what is to be done with a finished HTA report and with the recommendations given based on the report, with a clear pathway towards implementation. The scope of HTAs should be broad and include public health. HTAs should consider the whole health system with its interconnected services. <i>“A new medical device may reduce the need for pharmaceuticals [24].”</i> The scope of HTAs should include health system wide decisions, like <i>“where to concentrate specialized oncological services or where to establish a center of excellence for neurosurgery [24]”</i> . In terms of the currently lacking accessibility of completed HTAs and studies on HTA related topics done at universities, a system for archiving and retrieving these is proposed. |
| <b>cooperation of HTA doers for broader topics</b>    |  |
| <b>clear path towards implementation of HTA</b>       |  |
| <b>integrative whole system perspective for HTAs</b>  |  |
| <b>necessity to educate decision makers about HTA</b> | In terms of the image of HTA in Lithuania the need for the highest political echelon to in the future appreciate the importance of HTA in order for it to succeed is highlighted. In addition, decision makers should learn how to interpret the results of HTAs, how to distill the required information from HTA reports and how to put this information to use. The quality of HTAs is seen as key for its results to be taken seriously by the respective professional community.  |
| <b>quality of HTAs as key to their success</b>        |  |

### 3.3 Analysis of HTA institutionalization and financing

#### 3.3.1 International examples for HTA institutions and their resources

|   |   |
|---|---|
| <b>hardly an European country without one or several HTA institutions</b> | <p>Within INAHTA/The International Network of Agencies for Health Technology Assessment 55 non-profit organizations with at least 50% public funding (which is regarded as an indicator of a considerable stage of institutionalization [34]) are active members. Within EUnetHTA around 55 HTA institutions are collaborating. Due to the economic pressure on the health care systems, the ever increasing number of products brought to the market by industry and their extensive marketing activities, as well as demographic developments, the necessity for making decisions on the efficient use of health care resources is growing ever more pressing. HTA is regarded as a means of choice to rationally support this process. Today there is hardly an European country without one or several HTA institutions, sometimes units in different organisational environments.</p> <p>Even though HTA is in the process of becoming established and institutionalized both in individual countries and internationally, the majority (70%) of the total number of countries in the European region, and more than a half of EU countries do not yet have formalized HTA yet [34]: By “institutionalization of HTA” it is not necessarily meant that a national HTA-institute is founded, but that HTA is given a defined role in decision-making.</p> |
|---|---|

There is *not* one “best practice” model of HTA-institutionalisation in Europe, but many different models:

- ✿ Centralized: IQWiG/Germany, HAS/France, NICE/England, SBU/Sweden, ZIN/The Netherlands, NOKC/Norway, etc.
- ✿ (Partly of fully) Decentralized or regionalized: AETS, AETSA, AQuAS, AVALIA-T, OSTEBA/Spain; ASSR, RegVeneto, Reg Emilia Romagna and 2 national agencies: AGENAS, AIFA, Italy; etc.

HTA-coordinated networks with several profiled agencies: SNHTA/Switzerland; GÖG, LBI-HTA, DUK/Austria.

Nevertheless, the majority (around 80%) in EUnetHTA is publicly funded and closely associated with the government/ministry/health insurances: 42,5% are governmental agencies, 5% agencies within a compulsory (public) health care insurance, 32,5% are academic institutions [34]. And, since political investment and reimbursement decisions happen (often) under pressure from powerful professional groups (clinicians, industry), the independence of HTA is regulated in most countries. The guiding principles representing the basis of the working procedures of the HTA institutes are very uniformly defined by the cornerstones of “independent, objective and evidence-based, transparent scientific validity”.

Since HTA is *one* component of a broader health-care decision-making process that can best be described as a synergistic work-division between health policy, approval and reimbursement and HTA. Each component is defined and determined by distinctive functions and roles. HTA as the scientific part in the chain is characterized by critical appraisal and systematic synthesis of the available evidence. Summarized in the slogan “globalising evidence and localizing the decision” eventually recommendations are given, a decision is made. The independence from interest-groups and their influence as well as from political interference is an essential prerequisite for objective HTA-information. The independence, thus, is manifested within an agreed framework which is “based on the principle of good governance including transparency, objectivity, independence of expertise, fairness of procedure and appropriate stakeholder consultations” [2]. At the same time HTA needs to stay in arm’s length to health policy for providing relevant and timely answers to policy questions.

This repeatedly stressed independence from financiers and contracting agencies attempts to be reached through various mechanisms:

- ✿ Detailed Process and task descriptions
- ✿ Establishment of bodies and committees to monitor the scientific quality
- ✿ National and international Peer-Reviewing of all products
- ✿ Decoupling of recommendation (assessment, appraisal) and decision.

**many different models of institutionalization: not ONE best, but adapted to national conditions**

**all: publicly funded and closely associated with MoH and payers**

**HTA is *one* component in a synergistic work-division between health policy, approval and reimbursement**

**globalising evidence and localizing the decision**

**in arm’s length to health policy for providing relevant and timely answers to policy questions**

**independence and distance to interest groups for HTA of utmost importance**

|   |   |
|---|---|
| <p>changing conditions for HTA institutes: reduction of redundancies, supranational division of labor</p> <p>Europeanisation: embedding global evidence into national system knowledge</p>  | <p>At the same time – the EU is a common market – the high degree of redundancy in the processing of particular HTA issues is increasingly becoming more obvious. In the EUnetHTA “Planned and Ongoing Projects/POP-database” [35], a complete overlapping (same theme at the same point in time) in 10-12% of the HTAs (primarily in the assessment of new medicines and new procedures/devices after market entry, but before reimbursement) has become apparent. 30% of the HTAs address similar issues, such as disease patterns (e.g., depression, AIDS, dementia, rehab, etc.). The European network accordingly aims for a closer cooperation. With an increasing Europeanisation of HTA, it is essential to share global knowledge and to embed it into national system knowledge. In this way, the communication and coordination effort rises in favour of labour distribution and (hopefully) lowers the redundancy.</p> <p>Naturally, small countries have less capacities (resources) for comprehensive national HTA of critical numbers and therefore devote more time to international collaborations.</p> |
| <p>Scandinavian countries comparable to size of country: large investments in HTA</p> <p>decentralized/regional Spanish HTA (pop 2.1 million): 640.000 to 2.4 m.</p>                        | <p>Scandinavian countries, measured in terms of their population figures, invest comparatively much in HTA institutes involved in health care administration: EUR 8.85mio in Sweden/SBU (pop. 9.7mio), or EUR 3.7mio in Norway/NOKC (pop. 4.9mio), or 1.3mio in Finland/FinOHTA at THL (pop 5.4mio). The Mediterranean countries of Italy and Spain are characterised by many regional institutions and in part with distinctive profiles (only HTA for hospitals, only HTA for technologies/medicines after market entry, only horizon scanning). Resource deployment in two (small) Spanish is:</p> <ul style="list-style-type: none"> <li>✿ Basque Country/OSTEBA € 2.4mio (pop. 2.1mio) – 14 FTE (20 ongoing projects)</li> <li>✿ Galicia/AVALIA-T € 0.64mio (pop. 2.1mio) – 5 FTE (12 ongoing projects)</li> </ul>   |
| <p>Germany: IQWiG € 13m</p> <p>LBI-HTA: 1 comprehensive + 1,5 rapid HTA p.a. per researcher</p> <p>“good practice” examples for institutionalisation of HTA and impact on health policy</p> | <p>In larger countries (Germany: pop. 82mio) IQWiG has considerable more financial resources (EUR 13m).</p> <p>At the LBI-HTA (1,1mio budget, 8.3mio pop) with 14 FTE around 1 comprehensive HTA (6 months) + 1-2 rapid (STA, 2-3 months) can be produced by each of them 11 researchers. This is strongly dependent on additional activities (scientific publishing, dissemination activities, teaching, administration).</p> <p>The process of institutionalising a national HTA programme is a synthesis of top-down and bottom-up activities and relies on strong networking activities. The (human) resources invested in national HTA institutions or networks show a wide range, strongly depending on the mandate agenda (only HTA for drugs/devices or also comprehensive HTA or health services research, guideline development, horizon scanning).</p>   |

Table 3.3-1: Annual Budgets and FTE/Full Time Equivalents of European INAHTA-Members

| HTA Institution<br>EUROPE   | country                       | Resources for<br>HTA in EUR                    | Pop served<br>in Mio | FTE | URL   |
|---|-------------------------------|--|----------------------|-----|---|
| AETS – Agencia de Evaluación de Tecnologías Sanitarias                                    | Madrid, Spain                 | 746.000,00                                     | 0.04                 | 15  | <a href="http://www.eng.isciii.es/ISCIII/es/contenidos/">http://www.eng.isciii.es/ISCIII/es/contenidos/</a>               |
| OSTEBA – Basque Office for HTA  | Vitoria-Gasteiz, Spain        | 2.607.000,00                                   | 2.1                  | 14  | <a href="http://www.osanet.euskadi.net/osteba/en">http://www.osanet.euskadi.net/osteba/en</a>                             |
| KCE – Belgian Federal Health Care Knowledge Centre  | Brussels, Belgium             | 10.244.000,00                                  | 10.6                 | 45  | <a href="http://kce.fgov.be">http://kce.fgov.be</a>   |
| NOKC – Norwegian Knowledge Centre for the Health Services                                 | Oslo, Norway                  | 3.725.000,00                                   | 4.9                  | 50  | <a href="http://www.nokc.no">http://www.nokc.no</a>   |
| SBU – Swedish Council on HTA in Health Care   | Stockholm, Sweden             | 8.847.000,00                                   | 9.7                  | 60  | <a href="http://www.sbu.se">http://www.sbu.se</a>   |
| NETSCC, HTA – NIHR Coordinating Centre for HTA  | Southampton, UK               | 184.272.000<br>(all NETSCC managed programmes) | 64                   | 200 | <a href="http://www.hta.ac.uk">http://www.hta.ac.uk</a>   |
| ZIN – Zorginstituut Nederland   | Diemen, the Netherlands       | 9.591.000,00                                   | 16                   | 4   | <a href="http://www.zorginstituutnederland.nl/">http://www.zorginstituutnederland.nl/</a>                                 |
| ASSR – Agenzia Sanitaria e Sociale Regionale (Regional Agency for Health and Social Care) | Bologna, Italy                | 372.000,00                                     | 4.5                  | 5   | <a href="http://asr.regione.emilia-romagna.it/asr/index.htm">http://asr.regione.emilia-romagna.it/asr/index.htm</a>       |
| AQuAS – Agència de Qualitat i Avaluació Sanitàries de Catalunya                           | Barcelona, Spain              | 2.235.000,00                                   | 7                    | 54  | <a href="http://aquas.gencat.cat">http://aquas.gencat.cat</a>   |
| HIQA – Health Information and Quality Authority   | Dublin, Ireland               | 1.397.000,00                                   | 4.5                  | 7   | <a href="http://www.hiqa.ie">http://www.hiqa.ie</a>   |
| THL/FinOHTA – Finnish Office for HTA  | Helsinki, Finland             | 1.303.000,00                                   | 5.4                  | 27  | <a href="http://www.thl.fi/finohta">http://www.thl.fi/finohta</a>   |
| AVALIA-T – Galician Agency for HTA  | Santiago de Compostela, Spain | 652.000,00                                     | 2.7                  | 5   | <a href="http://avalia-t.sergas.es">http://avalia-t.sergas.es</a>   |
| AETSA – Andalusian Agency for Health Technology Assessment                                | Sevilla, Spain                | 839.000,00                                     | 7.5                  | 23  | <a href="http://www.juntadeandalucia.es/salud/servicios/aetsa/">http://www.juntadeandalucia.es/salud/servicios/aetsa/</a> |
| HIS – Healthcare Improvement Scotland   | Glasgow, Scotland, UK         | 652.000,00                                     | 5.1                  | 12  | <a href="http://www.healthcareimprovementscotland.org">http://www.healthcareimprovementscotland.org</a>                   |
| GÖG – Gesundheit Österreich GmbH  | Vienna, Austria               | 392.000,00                                     | 8.4                  | 6   | <a href="http://www.goeg.at">http://www.goeg.at</a>   |
| LBI-HTA – Ludwig Boltzmann Institut HTA   | Vienna, Austria               | 1.398.000,00                                   | 1.1                  | 14  | <a href="http://hta.lbg.ac.at">http://hta.lbg.ac.at</a>   |
| Age.na.s – The Agency for Regional Healthcare   | Rome, Italy                   | 4.977.000,00                                   | 60                   | 50  | <a href="http://www.agenas.it">http://www.agenas.it</a>   |
| AOTMiT – Agency for Health Technology Assessment and Tariff System                        | Warsaw, Poland                | 3.354.000,00                                   | 38.2                 | 40  | <a href="http://www.aotm.gov.pl">http://www.aotm.gov.pl</a>   |
| CEM – Inspection générale de la sécurité sociale (IGSS), Cellule d'expertise médicale     | Luxembourg, Luxembourg        | x  | x                    | x   | <a href="http://www.mss.public.lu/acteurs/igss/cem/index.html">http://www.mss.public.lu/acteurs/igss/cem/index.html</a>   |
| CEDIT – Comité d'Évaluation et de Diffusion des Innovations Technologiques                | Paris, France                 | x  | 12                   | 5   | <a href="http://cedit.aphp.fr">http://cedit.aphp.fr</a>   |
| HAS – Haute Autorité de Santé   | Paris, France                 | 931.000,00                                     | 65                   | 17  | <a href="http://www.has-sante.fr">http://www.has-sante.fr</a>   |

| HTA Institution<br>EUROPE   | country            | Resources for<br>HTA in EUR         | Pop served<br>in Mio | FTE | URL   |
|---|--------------------|-------------------------------------|----------------------|-----|---|
| DAHTA @DIMDI – German Agency for HTA at the German Institute for Medical Documentation and Information  | Cologne, Germany   | 777.000,00                          | 80                   | 11  | <a href="http://www.dimdi.de">http://www.dimdi.de</a>   |
| CRD – Centre for Reviews and Dissemination  | York, UK           | 4.004.000,00                        | 55                   | 56  | <a href="http://www.york.ac.uk/inst/crd/">http://www.york.ac.uk/inst/crd/</a>                           |
| SHAA – State Health Care Accreditation Agency under the Ministry of Health of the Republic of Lithuania | Vilnius, Lithuania | not separated from main SHAA budget | 3                    | 7   | <a href="http://www.SHAA.gov.lt">http://www.SHAA.gov.lt</a>   |
| IQWiG – Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen                                | Cologne, Germany   | 13.000.000                          | 82                   | x   | <a href="http://www.iqwig.de">http://www.iqwig.de</a>   |
| MTU-SFOPH – Medical Technology Unit – Swiss Federal Office of Public Health                             | Bern, Switzerland  | x                                   | 8.0                  | 6   | <a href="http://www.snhta.ch">http://www.snhta.ch</a>   |
| UVT – HTA Unit in A. Gemelli Teaching Hospital  | Rome, Italy        | x                                   | 58                   | 10  | <a href="http://www.policlinicogemelli.it/area/?s=206">http://www.policlinicogemelli.it/area/?s=206</a> |
| HTA-HSR/DHTA – HTA & Health Services Research   | Århus, Denmark     | 745.000,00                          | 5.5                  | 9   | <a href="http://www.mtv.rm.dk">http://www.mtv.rm.dk</a>   |



### 3.3.2 Analysis of existing HTA resources in the Lithuanian health system

Lithuanian HTA is currently chiefly carried out by two institutions, both under the MoH, with defined content areas. Both institutions (SHAA, IoH) benefit from EU funded projects:

- ✿ State Health Care Accreditation Agency (SHAA) for medical devices
- ✿ Institute of Hygiene (IoH) for Public Health and
- ✿ possibly in the future State Medicines Control Agency SMCA for pharmaceuticals: SMCA is applying for EU structural funding in 2016

A small hospital-based HTA unit has been established at Kaunas university hospital.

**HTA in SHAA,  
IoH and at a hospital  
based HTA unit**

#### Mapping resources: estimation of FTE already working in HTA

SHAA's Medical Technology Section with a staff of 7, works on HTA. 5 employees work on doing HTAs full time. The individual authors of SHAA HTA reports are not disclosed. So far SHAA completed 6 HTAs and is currently working on 4 topics. The topics for the HTAs on medical devices either come from manufacturers, that can apply for an HTA at SHAA, or from the MoH or from the National Cancer Institute.

**resources at SHAA:  
5 full-time HTA doers**

According to the publicly available information on 2 July 2015, SHAA completed and published abstracts of 6 HTAs:

1. "Assessment of breast tomosynthesis diagnostic efficacy in diagnosing breast cancer";
2. "Assessment of breast ultrasound scan diagnostic efficacy in diagnosing breast cancer";
3. "Assessment of duplex flow radioabsorbtiometrix and quantitative computer tomography methods in diagnosing osteoporosis";
4. "Cochlear implant efficacy to cure adult and children deafness";
5. "Treatment of surgical type 2 diabetes: assessment of stomach surgeries";
6. "Surgical treatment of urinary incontinence: assessment of implantation surgery of artificial sphincter for men".

**SHAA so far published  
abstracts of 6 HTAs on  
medical devices**

Only the summaries of the conducted HTAs are publicly available on SHAA website: <http://www.vaspvt.gov.lt/node/486>.

Judged on the published summaries the HTA reports include the following sections: reasoning the HTA need; methods used; the review of the assessment (focusing on the pricing and life quality statistics); conclusions (on life quality statistics and complications); assessment of limitations to conclusions (e.g. scarcity of source materials); recommendations (as to whether and when to apply the technology; the impact of the technology on life quality, public expenses).

|  |   |
|--|---|
| <p><b>resources at Institute of Hygiene IoH:</b><br/><b>8 full-time HTA doers</b></p> <p><b>so far 3 HTAs completed, 1 ongoing</b></p> | <p>The IoH is responsible for HTA in public health, presently has a staff of 12 involved in HTA, 8 of them doing HTA full-time. HTA staff is active in two separate, but cooperating Centers at the IoH: Occupational Health and Public Health. So far the IoH has completed 3 HTAs (2 published). The topics were prioritized internally through a Delphi process with stakeholders, and also suggested by the MoH. The IoH is in the process of building HTA procedures for its further activities. Summaries of the 2 HTA reports are published:</p> <ol style="list-style-type: none"> <li>1. “Screening and short intervention for prevention of alcohol misuse” (see <a href="http://technologijos.hi.lt/uploads/pdf/Alkoholis%20_santrauka_viesinimui.pdf">http://technologijos.hi.lt/uploads/pdf/Alkoholis%20_santrauka_viesinimui.pdf</a>);</li> <li>2. “Effectiveness of Physical Activity Interventions in the Workplace” (see <a href="http://technologijos.hi.lt/uploads/pdf/FA%20_santrauka_viesinimui.pdf">http://technologijos.hi.lt/uploads/pdf/FA%20_santrauka_viesinimui.pdf</a>).</li> <li>3. “Effectiveness of interventions to promote physical activity among adults and practice of interventions in Lithuania” (unpublished).</li> </ol> |
| <p><b>resources at SMCA:</b><br/><b>unclear, likely none</b></p>   | <p>Published summaries refer to HTAs performed under the EU structural funds framework. The third completed HTA (unpublished) is entitled</p> <p>At present the IoH is working on two further HTA projects:</p> <ol style="list-style-type: none"> <li>1. “Telephone counselling for smoking cessation”.</li> </ol>   |
| <p><b>resources at university hospitals:</b><br/><b>one small hospital-based HTA unit at Kaunas University Hospital</b></p>            | <p>Currently there are no HTA activities at the SMCA. No public information is available as to what extent SMCA staff is planned to be involved in HTA activities in the future.</p> <p>In 2014 the first Lithuanian hospital-based HTA unit was established at Kaunas University Hospital and staffed with half a full-time equivalent position supported by a Masters student. The unit serves to present the HTA-evaluations to the clinic administration for the decision making whether to acquire new technologies.</p>   |
| <p><b>resources at MoH:</b><br/><b>HTA Committee</b></p>   | <p>There are also some HTA related activities at Medical Associations that prepare guidelines.</p> <p>In 2014 a HTA Committee was established at the MoH (see details in 3.1.2.2.) The composition of the Committee with high level MoH representatives suggest that the Committee is designed to decision making on a rather strategic level. In fact, the most of MoH representatives within the Committee have minor involvement in HTA activities outside the Committee.</p>  |
| <p><b>private sector consultants (paid by industry) are offering pharmacoeconomic input for application for reimbursement</b></p>      | <p>A number of private entities exist that declare an involvement in HTA. These are mostly single consultants offering marketing authorisation acquisition and maintenance, assistance in enrolling medicinal products into reimbursement schemes, medicinal product risk benefit ratio assessments for pharmaceutical companies.</p> <p>To our knowledge medicinal product pharmaco-economic assessment is offered by the following companies: UAB “Diavera”, UAB “Farmanis”, UAB “Maras”.</p>   |
| <p><b>resources in academic research:</b><br/><b>LUHS – Kaunas, Mykolas Romeris Univ. – Vilnius, Vilnius Univ.</b></p>                 | <p>The Lithuanian capacity for academic HTA research is located at 3 universities:</p> <ol style="list-style-type: none"> <li>1. Lithuanian university of health sciences (LUHS), Kaunas (health economics and HTA)</li> <li>2. Mykolas Romeris University, Vilnius (health system and health policy)</li> <li>3. Vilnius University (VU), Vilnius (public health, epidemiology, health statistics, HTA)</li> </ol>   |

## Evidence based medicine movement and HTA

Active promotion of evidence-based medicine has started in 2013 when two medical students from Oxford University organized an Evidence based medicine conference and invited internationally recognised speakers. The second Evidence based medicine conference was organized in Kaunas in partnership with lecturers from Lithuanian university of health sciences in 2014. The target audiences of the conference are students, residents, PhD students and young doctors. It is planned to organize a third Evidence based medicine conference in autumn 2015.

**first local evidence based medicine conference in 2013**

In summer 2014, virtual evidence based medicine centre was established at the Clinic of Internal Medicine, Family Medicine and Oncology in accordance with decision of the Faculty of medicine council of Vilnius University. The aim of the Virtual evidence based medicine centre is to improve health care, by disseminating the highest grade clinical evidence and developing skills in finding evidence, critical appraisal and properly adapt to their patients. Virtual evidence based medicine centre may serve as a partner to the SHAA and IoH to promote HTA to professional community.

**in 2014 Vilnius University established a "virtual evidence based medicine centre" to disseminate information and help develop skills**

## Role of Physicians: Evidence Based Medicine Guidelines and Clinical Pathways

There is no single coordinating institution for development and implementation of clinical guidelines and diagnostic and treatment pathways. Although 42 clinical methodologies (guidelines) are presented on the MoH website at present, only few of them are prepared in accordance with Agree II criteria for quality and reporting of practice guidelines. Short recommendations for preparation and implementation of diagnostic and treatment methodologies (guidelines) and descriptions of procedures were approved by the MoH in May 2006<sup>72</sup>. This document sets basic requirements for guideline structure, coordination and publication, however, it is insufficient to develop a quality document.

**no coordinator for guidelines and clinical pathways in Lithuania**

**MoH published methodological recommendations**

Two high value projects on clinical guidance and diagnostic and treatment pathways development were launched in 2013.

As a part of Lithuanian – Swiss Cooperation Programme funded project "Improvement of perinatal and neonatal health care services in Lithuania", 70 evidence based clinical guidelines (30 in neonatology and 40 in obstetric) were developed in 2014. Each guideline was prepared by the multidisciplinary team of physicians from Vilnius, Kaunas, Siauliai and Marijampole hospitals, and comprises 5 components: description of methodology, description of procedures, implementation inventory, audit inventory and information for the general public.

**2 clinical guidelines flagship projects:**

**... perinatal and neonatal care (funded by Switzerland)**

---

<sup>72</sup> Description of procedures for drafting and implementation of diagnostic and treatment methodologies approved by 17 May 2006 order No V-395 of the Ministry of Health

...cardiology,  
traumatology,  
neurology,  
paediatrics,  
oncology  
(funded by EU)

In 2014-2015 within the EU structural funds project UAB EVP group has developed 123 pilot diagnostic and treatment protocols (pathways) in the fields of cardiology, traumatology, neurology, paediatric and oncology<sup>73</sup>. Each pathway was drafted in the group of experts led by expert physician with a scientific degree, following a standardised drafting and implementation algorithm. All protocols were developed following the new MoH Order for preparation, review and renewal of diagnostic and treatment protocols<sup>74</sup> requiring each protocol to cover only one disease, syndrome, condition or procedure and to be revised at least once every three years by health care institutions.

### 3.4 Analysis of human resources and capacity building

#### 3.4.1 International examples of human resources in HTA and capacity building for “emerging” countries

from selective/biased  
decision-making to  
evidence-based  
decision-making

Even though a formal HTA programme might not be in place in some countries, decision-making about the adoption of new technologies is part of the operational routine of health authorities and health service providers. Such decisions are frequently based on unilateral industry information or single experts. The challenge is to change the decision-making culture towards evidence-based decisions. This change requires – beside the firm commitment from health policy (health authorities) – sufficient national capacities to carry out HTA [34].

concept of capacity  
building:  
training to conduct HTA  
training to understand  
and implement HTA

Therefore the concept of capacity building encompasses

- ✿ not only the training of HTA core staff,
- ✿ but also the involvement of existing (relevant) capacities in other academic institutions (universities), and
- ✿ also the sensitization of key stakeholders.

#### Human resources in European HTA Agencies

due to the broad range  
of HTA-topics  
  
need for  
multi-disciplinarity

The diversity of the subjects within Health Technology Assessment requires a broad range of different competences in human resources: content-wise and methodologically. HTA is by definition multi-disciplinary: the availability and recruiting of trained staff is considered a scarce resource and an important barrier even in countries with long-standing HTA tradition [34].

<sup>73</sup> Diagnostic and treatment protocols (project). Ministry of Health. Retrieved July 1, 2015, from <http://www.sam.lt/go.php/lit/Diagnostikos-ir-gydymo-protokolai-Projektas>

<sup>74</sup> Order for preparation, review and renewal of diagnostic and treatment protocols approved by the 2 December 2014 order No V-1248 of the Ministry of Health

Staff in HTA comprise researcher from different fields:

- ✱ Staff at HTA-institutions: information-specialist, specialists in medicine, biology, pharmacology, genetics, epidemiology, economics, psychology, communication, public health, nursing, social science, communication etc.
- ✱ External staff: clinical specialists, statistics, modelling etc.

**medicine, epidemiology,  
social science**

The required number of human resources is highly dependent on the mandate of the HTA agency. Covering the full range of human resources is not always possible, therefore a strong network of external collaborating experts in specialized fields of medicine and/or methodology is a pragmatic and flexible solution for many HTA institutions. Considering this option of “outsourcing” resources for commissioning must be available and the training of HTA skills for the collaborating experts must be considered (and arranged).

**outsourcing,  
commissioning**

**also training**

To also involve the external experts in HTA training can be considered as part of growing fundament for the culture of evidence-based health care.

**part of a growing  
culture of evidence-  
based health care**

## Capacity Building: Training to conduct HTA

Owing to the multi-disciplinarity of HTA, human resources must be adequately trained in order to cope effectively with the wide range of possible HTA-topics. Besides the basic academic education in the respective discipline of the researcher, training in HTA specific methodologies is required:

**HTA training**

- ✱ Systematic literature searches in different databases, documentation of the search-strategy, administration and handling of literature selection, retrieval, documentation in PRISMA, citation, etc.
- ✱ Quality assessment and critical appraisal of clinical studies with established assessment instruments, knowledge of, assessing and avoiding of biases, etc.
- ✱ Extracting data and synthesizing the evidence (qualitative, quantitative/meta-analysis, decision-analysis etc.)
- ✱ Arriving at and formulating recommendations with established instruments (GRADE).
- ✱ Writing and publishing the results for different target audiences.

**systematic  
literature searches  
critical appraisal  
bias and quality  
assessment  
extracting and  
synthesizing  
recommendations**

## Capacity Building: Training to understand and implement HTA findings

The communication with the decision-makers is of essential importance for the actual utilization and implementation of HTA findings. Presentations for policy and decision-maker must encompass

**training for  
decision-maker**

- ✱ Possible utilizations of HTA customized to the audience
- ✱ Projects that proof the concept (impact on savings or on risk reduction)
- ✱ Some examples showing the difference in outcome between biased/selective and evidence-based research findings

**selective vs.  
systematic reviews  
options for HTA  
utilization**

## Networking, “partnering” and collaboration

**national HTA efficiency  
relies on HTA transfer  
from other countries +  
on collaborations**

Since esp. small countries can never have the capacities (such as NICE/UK) to assess all new technologies and interventions before their introduction, or for other HTA utilizations,

- ✿ skills to use others’ assessments in the national context and
- ✿ relations for collaborative assessments

are essential also for national efficiency.

**strong external  
networks and  
collaborations**

Strong external networks with institutional partners and within HTA-networks (EUnetHTA, INAHTA) are of utmost importance, but need time and resources to establish and to foster to create a working environment of mutual trust. With the increasing Europeanisation due to EUnetHTA the exchange of staff for a certain period is one concept to learn from established institutions or on processes elsewhere.

## 3.4.2 Analysis of existing training in HTA and capacity building in Lithuania

### Mapping the landscape of advanced training/ capacity building for HTA staff

**continuing medical  
education (CME)  
mandatory for doctors,  
nurses, pharmacists**

Continuing professional education for doctors, nurses and pharmacists in Lithuania, as well as in other Eastern and Central European countries (except for Estonia) is mandatory. Within five years, physicians and pharmacists<sup>75</sup> must to devote at least 120 hours and nurses – at least 60 hours<sup>76</sup> for professional development. Continuing education for public health professionals is neither compulsory nor regulated.

**CME for public health  
professionals neither  
compulsory nor  
regulated**

Various professional development forms are legitimate in Lithuania: courses, internships, lectures, presentations, publications in peer reviewed journals and their annual subscriptions, scientific conferences, seminars, international congresses, studies. Distance learning is also available for continuing medical education. 1 credit hour of continuing medical education course in Lithuanian educational institutions equals to 1 academic hour (45 min.), whereas 1 academic hour spent in international scientific congress or conference (both in Lithuania or other country) is equated to 1.5 credit hours. In accordance with European Accreditation Council for Continuous Medical Education (EACCME) rules, no more than 3 CME credits are awarded for a half-day course and 6 CME credits a for a full-day course. Course duration is not restricted in Lithuania.

**universities or  
institutions approved by  
MoH can issue CME  
credits**

Only institutions that provide training programmes (conferences, lectures, courses, etc.) approved by the Ministry of Health are eligible to issue the mandatory CME credits. Training programs in fields of personal health and pharmaceuticals are administered by the Training and Specialization Centre for Nursing Personnel. The Centre for Health Promotion and Disease Pre-

<sup>75</sup> Procedure on improvement and financing of professional qualification of health care specialists and pharmacists approved by 18 April 2002 order No 132 of the Ministry of Health.

<sup>76</sup> Description of procedures for authorisation and renewal of nursing licences and certificates approved by 1 November 2001 order No V-512 of the Ministry of Health (updated by 29 June 2001, order No V-549).

vention administers public health programmes. Training programmes developed by specialized universities and colleges as well as hospitals of Vilnius university and Lithuanian university of health sciences do not need an approval from the Ministry of Health.

Health professionals are also able to obtain mandatory CME credits from formal educational institutions in the EU member states, Switzerland or the EEA states.

CME courses of Vilnius university and Lithuanian university of health sciences are administered through the information system entitled MEDAS ([www.medas.lt](http://www.medas.lt)). Educational programs of other institutions are administered through NHIF information system SVEIDRA subsystem METAS (<http://kvp.vlk.lt/METAS/>).

The mandatory continuing education system of Lithuania is not favourable to the application of HTA principles in the country. Training in the field that is not obligatory for the participant (e.g. a physician takes a course in pharmacy, economics, information technology, finance, management, social work, sociology, statistics, law etc.) is awarded with only 1/3 CME credit hour per hour of training. At present, there is no programme for HTA, although system of formal continuing education offers several courses related to this assessment.

We have searched METAS and MEDAS databases trying to retrieve courses in health care management, hospital management, public health and health services, epidemiology, medical statistics, health economics and evidence based medicine. Table 3.4-1 below summarizes the results.

**non mandatory content  
of CME – like HTA – is  
dis-incentivized**

**currently no CME  
program for HTA**

Table 3.4-1: List of continuing medical education courses attributed to HTA in Lithuania

| Subject                                     | Vilnius University |   | Lithuanian university of health sciences |   | Other providers |  |
|---|--------------------|---|--|---|-----------------|--|
|   | N                  | Title/Provider/Target audience  | N  | Title/Provider/Target audience  | N               | Title/Provider/Target audience   |
| Public Health                               | 0                  |   | 1  | Public Health Surveillance/Department of Health Management/Public health professionals  | 6               | 1. Public Health Surveillance/Institute of Hygiene/ Public health professionals;<br>2. Health Impact Assessment (3 programmes)/ Centre for Health Promotion and Disease Prevention/Public health professionals;<br>3. Development and implementation of public health programmes/Centre for Health Promotion and Disease Prevention/Public health professionals;<br>4. The modern concept of public health/Centre for Health Promotion and Disease Prevention/Public health professionals  |
| Health care management/ Hospital management | 4                  | 1. Management of medical services/Clinics of Internal medicine, Family medicine and Oncology/Physicians<br>2. Quality management of health care laboratories/Department of physiology, biochemistry and laboratory medicine/ Department Physicians, biologists<br>3. Methods for biochemical testing and quality management/Department of physiology, biochemistry and laboratory medicine/Physicians, biologists<br>4. Health care management innovations in public health/Public health institute/Public health professionals | 5  | 1. Quality management in health care/ Department of Health Management/ Physicians<br>2. Teamwork and case management in outpatient mental health care system/Institute for behavioural medicine/various<br>3. Basics of management and health economics/Department of Health Management/Public health professionals<br>4. Health care Management/Department of Health Management/Nurses<br>5. Assurance of nursing quality/Department for nursing and care/Nurses | 7               | 1. Development of the system for monitoring of qualitative and quantitative indicators of for health care services providers/Vsl Safety and quality experts Bureau/Physicians, nurses<br>2. Development and implementation of process for medical devices management for in health care institutions/Vsl Safety and quality experts Bureau/Physicians, nurses<br>3. Development of the internal quality system and audit documentation in health care institution/ Vsl Safety and quality experts Bureau/ Physicians, nurses<br>4. Patient services quality management in health care institution (3 programmes)/UAB Centre for Human Studies/Physicians, nurses<br>5. Systematic management of the personnel of health care institution)/UAB Centre for Human Studies/Physicians, nurses<br>Basics of management and economics/Centre for Health Promotion and Disease Prevention/Public health professionals |



| Subject                                  | Vilnius University |  | Lithuanian university of health sciences |  | Other providers |                                |
|--|--------------------|--|--|--|-----------------|--------------------------------|
|  | N                  | Title/Provider/Target audience   | N  | Title/Provider/Target audience   | N               | Title/Provider/Target audience |
| Epidemiology                             | 1                  | Epidemiological research planning and data analysis/Public health institute/Epidemiologists      | 0  |  | 0               |                                |
| Medical statistics                       | 1                  | Basic statistics for inequalities assessment/Public health institute/Public health professionals | 1  | Health statistics/Department of preventive medicine/Physicians   | 0               |                                |
| Evidence based medicine/Health economics | 0                  |  | 2  | 1. Evidence-based intensive care and economic evaluation/Intensive care clinic/Physicians<br>2. New paradigm for nursing development: from evidences to actions/Department for nursing and care/Nurses | 0               |                                |

**28 CME programs tailored for physicians and nurses, many with a management focus**

In total 28 CME programmes were identified. Almost half of the programmes were in the field of health care or hospital management and most of them were offered for physicians and nurses training.

Governmental public health institutions (Hygiene Institute, Centre for Health Promotion and Disease Prevention) and universities focus their trainings on specialty groups (e.g. public health professionals, physicians), while private entities offer services for combined target groups (courses for both – physicians and nurses).

### 3.5 Analysis in HTA processes and products, special focus assessment of medical devices

#### 3.5.1 Generic “good practice” in HTA processes and products

**positioning of HTA in knowledge chain**

The “knowledge value chain” in the healthcare sector is helpful to position HTA in the wider field. The knowledge value chain spans from basic research on through the domains covered by HTA (synthesis, assessment, appraisal), then to the health policy field of decision making until the phases of dissemination and finally implementation (utilization) in practice (see Figure 3.5-1) and monitoring of effects and impact. These steps however are not distinct from each other: There will often be interaction between the steps of assessment, appraisal and decision-making, e.g. through the initial health policy influence on choosing the question an HTA should answer.

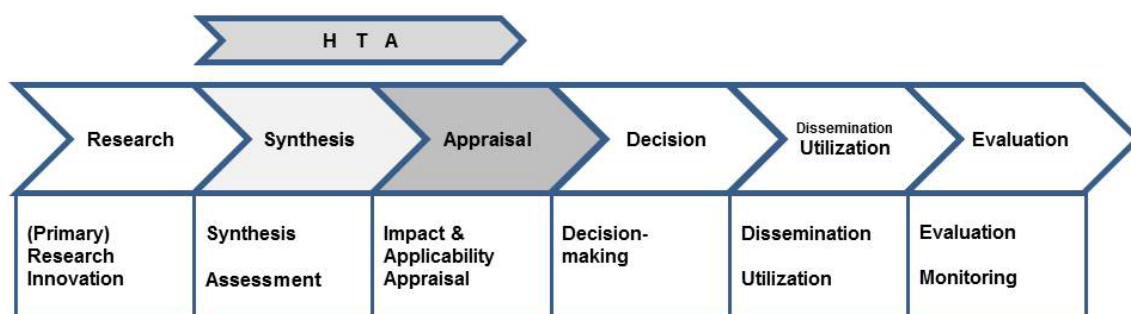


Figure 3.5-1: Knowledge value chain in the health sector. Source: developed from [36]

**the building blocks of HTA**

**transparency in process and products make the results open to scrutiny**

**of special importance in circumstances of criticism or conflict**

HTA as a research-based and user-oriented assessment of relevant available knowledge has (see Figure 3.5-1) a bridge function between the domains of research and policy decision-making. HTA does not make complexity disappear but offers a structure for taking multifaceted decisions. After it is clarified that a certain policy question raised at the outset is suitable for an HTA, an HTA question is derived. In the actual research phase of HTA, best available evidence from various areas and perspectives is brought into the thorough analysis and assessment. Since HTAs have consequences on health policy decisions on procurement, reimbursement and planning it is of utmost importance that the process and the products of HTA are transparent and traceable: the systematic approach to searching, to extracting and to summarizing data and the disclosure of all methods make the results open to scrutiny.

This is especially important in circumstances of criticism or conflict with stakeholders (clinicians, manufacturer, patients).

Several national handbooks and HTA-methods guidelines present the phases of HTA: Denmark [37], England [38], Austria [39]. NICE [38] has a special focus on involvement and participation of stakeholders including independent academic groups, manufacturers and sponsors, patient and carer groups, healthcare providers and commissioners of health services, clinical specialists, commissioning experts and patient experts. Even if “good practice” standards are established for HTA decisions on the adaption to the national context of the process is necessary. Decisions have to be made.

It is essential to know (not to forget) that HTA has most impact if associated (bound to) actual health policy decision to be taken.

The accepted characteristics of HTA (clear formulation of the problem, explicit methodology, a wide view on the technology beyond safety and effectiveness) [40] are illustrated in greater detail in the HTA assessment process towards best practice of Figure 3.5-2 below. An HTA is initiated either through the identification of an assessment need (system-perspective of HTA need) or through the submission of an assessment request (applicant’s initiative of HTA need). In most health care systems both options for HTA topic generation take place, since leaving the HTA-agenda only to submission-driven technology assessments would mean to limit the HTA spectrum to products rather than to processes/procedures or human resources-intensive interventions.

Options to decide are:

- ✱ *Submission-based assessments (of pharma or device products):* the submission constitutes the basis for assessment (Model BAG/Switzerland: Applicant has to deliver full HTA, HTA-agency “controls” only application).
- ✱ *Procedure-based assessments:* **not** single devices, but the intervention in a specific indication (with ev. different devices) is issue of the HTA (Model IQWiG/Germany).
- ✱ *Comparative effectiveness HTA:* all comparators (also watchful waiting) are considered (Model: AHRQ/USA).
- ✱ *Relative effectiveness HTA:* the technology (device, drug) in question is compared to competing technologies (devices, drugs).
- ✱ Research-initiated HTAs
- ✱ Public or expert consultation on needs for HTA
- ✱ Etc.

Due to the fact that HTA resources have to be used as efficiently as health care resources, priorities on commissioning have to be set [41]. Prioritisation can be carried out in a number of ways depending on resources and time available, transparency of process and who is involved. Rarely it will be possible to assess all new and some old interventions. In general HTA resources will be used for “high volume and high costs interventions with a high amount of uncertainties”. To use explicit criteria might be of help under political pressure.

multi-step in process  
good practice  
established

but:  
adaptation to national  
context necessary

options!

a generic process of  
HTA assessment  
towards best practice

topic initiation of HTA:  
identification of need  
for HTA or  
submission

options for topic  
identification for HTA

priority setting

|  |  |
|--|--|
| <b>options for priority setting for HTA</b>    | <p>Options to decide are:</p> <ul style="list-style-type: none"> <li>✿ Formal priority setting process [42] based on criteria (e.g. [43]) for deciding committee.</li> <li>✿ Informal, discussion- and consensus based process on HTA necessities deciding committee.</li> <li>✿ Public or expert consultation on prioritization.</li> </ul> <p>The demand for HTAs is subsequently prioritized and an HTA on a particular health technology is commissioned.</p>  |
| <b>policy questions: essential information</b> | <p>In the next step the policy questions are defined and the HTA protocol is elaborated. The policy question reflects the context in which the assessment is carried out [44]:</p> <ul style="list-style-type: none"> <li>✿ Who initiated the report? Who commissioned it? (policy-maker, health care manager/administration, 3<sup>rd</sup> party/manufacturer, patients' advocate, HTA-institution).</li> <li>✿ Why is an assessment needed right now? (new technology, new indication, structural/organizational changes, safety/ethical concerns, old technology etc.).</li> <li>✿ Which decision is the assessment going to support? (investment decision, market approval, planning, in-/exclusion benefit catalogue, planning of capacities, guidance on best practice, investment in research, organization of service provision).</li> <li>✿ Who represents the primary target audience for the report? (political decision-makers, 3<sup>rd</sup> parties/manufacturer, hospital managers, clinicians).</li> </ul> |
| <b>scoping</b>                                 | <p>In this so called “scoping” phase of developing a research questions feasible to answer the policy question (translation), background materials for orientation and for determination of (development and diffusion) status the technology are gathered. Options for “scoping” are:</p>   |
| <b>options for scoping</b>                     | <ul style="list-style-type: none"> <li>✿ Meeting with experts (e.g. clinicians in the respective medical field) in order to understand e.g. comparators, organizational and infra-structural needs and other influential factors etc.</li> <li>✿ Development of HTA-protocol based on published materials. Obtaining of written feedback by experts (via mail).</li> <li>✿ Even public consultation of HTA project-protocol is possible [45] (Model IQWIG/Germany; KCE/Belgium: Patient involvement for definition of critical endpoints).</li> </ul>  |
| <b>development of HTA protocol</b>             | <p>In order to give an evidence-based answer to the problem outlined in the policy question, formulating the actual research question is a crucial part in the process. Based on this “scoping” process an HTA protocol has to be written. The PICO (Patient-Intervention-Control-Outcome) scheme supports this step by focusing on a (clinical) question in terms of the specific patient problem and is aiding the searcher (info-specialist, librarian) in finding (clinically) relevant evidence in the literature.</p>  |
| <b>options for scale and lengths of HTAs</b>   | <p>Depending on the time-frame and the complexity of the topics, options to decide are:</p> <ul style="list-style-type: none"> <li>✿ Rapid assessment (1-3 months) for single technologies</li> <li>✿ Multiple comparative technologies (3+ months)</li> <li>✿ Comprehensive assessments for complex interventions (6+ months)</li> <li>✿ Planning documents</li> <li>✿ Etc.</li> </ul>  |

HTA is a multi-disciplinary research activity. Methodologic guidances on the actual development of an HTA on

- ✿ Systematic searching (in different databases)
- ✿ Critical Appraisal and quality assessment
- ✿ Extracting and validating of outcome data (on selected patient relevant endpoints)
- ✿ Reporting of results

are to be found elsewhere in manifold handbooks, appraised and synthesized in the EUnetHTA methods-guidances [34].

While in rapid assessments on single technologies (drugs/devices) an evidence analysis of safety and efficacy/effectiveness might be sufficient, the assessments of other technologies require information on also psychological/social/ethical implications, on organizational/professional effects and economic impact of a technology. Besides background materials on the health problem in question and on the technology (intervention) itself, it is essential to start with assessing safety and efficacy/effectiveness first – provided information on (low, acceptable) risk and (high, certain) benefit given –, since subsequent assessments (e.g. on economics) might not be needed if previous ones already provided a negative answer.

For each of the “domains” (safety, efficacy/effectiveness etc) studies are identified (in several sources/databases), selected according to pre-defined criteria, the quality of the evidence is appraised, the evidence extracted and the patient-relevant information synthesized. The results from all outcomes form the basis of the discussion and the conclusion of the HTA [40]

Peer reviewing as a measure of external quality control is considered an essential last step before publication.

Options for the evidence synthesis (HTA) are (also based on the time-frame):

- ✿ Inclusion of unpublished information (grey publications, unpublished primary data).
- ✿ Drafting of recommendations (or conclusions only), use of grading tools (GRADE).
- ✿ Quality assurance measures: number of peers reviewing the HTA (e.g. methodologist and clinical expert or only clinical expert). Selection of peers.
- ✿ Conflict of Interest (CoI) statements and their management.
- ✿ Public consultation and stakeholder involvement [45, 46] of final draft. Publication of all stakeholder comments and authors’ responses.

**evidence analysis  
and assessment:  
methods handbooks**

**EUnetHTA methods  
guidance**

**multi-disciplinary  
multidimensional**

**transparency in all steps  
of the evidence analysis:  
from search to selection  
to extraction to  
reporting**

**options in the  
development of  
the assessment**

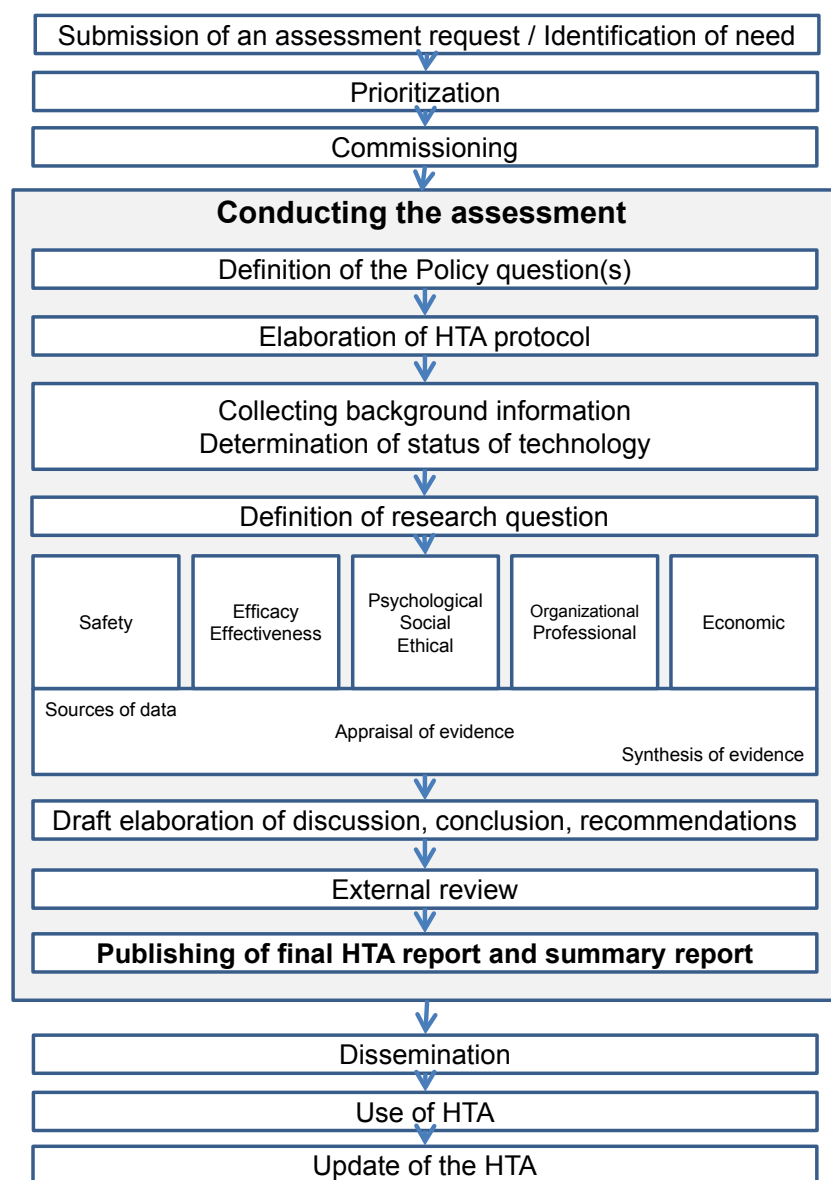


Figure 3.5-2: Best practice HTA assessment process. Source: [40]

#### Excursus:

#### The EUnetHTA pilot process of rapid assessments of medical devices

**EUnetHTA:**  
**extensive stakeholder**  
**involvement**  
  
**and consideration of**  
**their inputs**

Within EUnetHTA Joint Action 2 a process for piloting rapid assessments of relative effectiveness (REA) for other technologies [than pharmaceuticals] such as medical devices, surgical interventions or diagnostics was developed. In this process, a special focus lies on stakeholder involvement.

- ✿ In the scoping phase of the assessment different stakeholders including manufacturers may submit topics for assessment.
- ✿ After a topic has been selected and the cooperating HTA doers have been identified, manufacturers hand in their submission file and a scoping meeting takes place.

- ✳ In the meantime a public consultation via the EUnetHTA website collects inputs on the draft project plan from a wider group of stakeholders including consumers, patients and medical experts. The authors of the rapid assessment answer all comments.
- ✳ The resulting final project plan is the basis for the ensuing assessment phase with two review cycles, one internal among the project group of HTA doers and one external with at least two outside experts. The comments of the external reviewers are answered and later published together with the report.

After medical editing and formatting, the final version of the pilot relative effectiveness assessment is translated for incorporation into national and local HTA reports. The relative effectiveness assessment does not contain recommendations regarding reimbursement. All HTA doers involved in the process as well as the external reviewers complete a declaration of interest to make potential conflicts of interest transparent. EUnetHTA's proposed process comes with a detailed timeline [47] and is visualized in Figure 3.5-3.

**no recommendations  
Col Management**

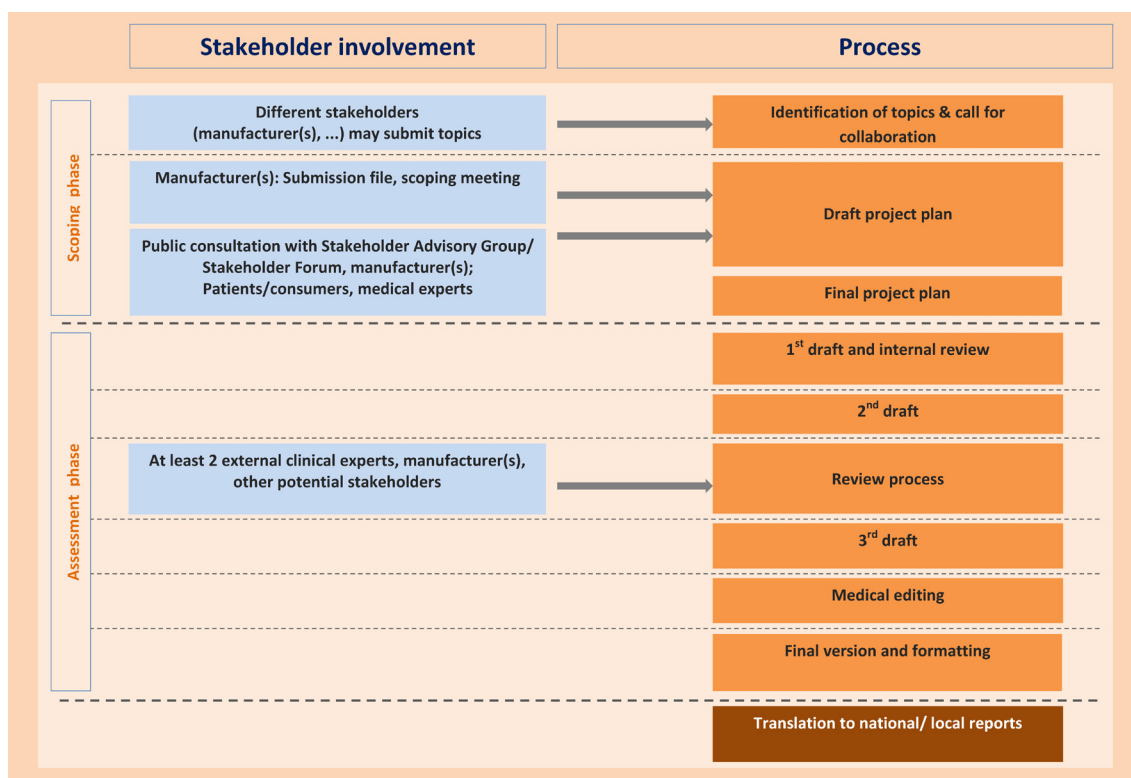


Figure 3.5-3: EUnetHTA Joint Action 2 Pilot process of rapid assessments of “other technologies” such as medical devices, surgical interventions or diagnostics. Source: simplified from [47]

## Dissemination, communication, publication

|  |   |
|--|---|
| <b>dissemination activities</b>                              | A crucial, often underestimated activity is that of dissemination of the HTA-products. The target audience of HTA is frequently not limited to policy makers. The ability to increase the use of the findings not only by decision makers, but also by clinicians is part of a changing culture towards evidence-based policy making and evidence-based clinical practice [48]. The awareness that dissemination activities need to be intensified increased in recent years. |
| <b>options:</b>  | Options are   |
| <b>passive dissemination (public access on website etc.)</b> | <ul style="list-style-type: none"> <li>✿ Passive dissemination via website access or open access with 1-time information for identified target group (e.g. clinicians).</li> <li>✿ Active dissemination via presentations in national clinical fora.</li> </ul>   |
| <b>active dissemination: presentations</b>                   | <ul style="list-style-type: none"> <li>✿ Active awareness raising in for a of decision-makers.</li> <li>✿ Active network-management and communication (starting with inclusion of clinicians in scoping and peer-review).</li> </ul>  |
| <b>communication to target groups etc.</b>                   | <ul style="list-style-type: none"> <li>✿ Patient-information.</li> </ul>  |

## From assessment to appraisal to structured decision-making [49]

|  |  |
|--|--|
| <b>assessment = collection and synthesis of evidence</b>                       | HTA is based on a stringent methodology giving special importance to the traceability of the results and to equi-distance to interest groups in order to avoid undue influence. In some, but not all instances scientific evidence of sufficiently high quality that can directly lead to a clear-cut policy decision is lacking. In addition uncertainty and social or institutional values (e.g. equity) need to be addressed. As a result the need for an additional value-based activity arises. Contextualizing the evidence and framing recommendations is carried out in an appraisal of the evidence synthesized in the prior assessment step. |
| <b>appraisal = contextualizing evidence and formulation of recommendations</b> |  |

A few European countries (UK, NL) make a clear distinction between HTA (with or without recommendations developed), Appraisal (for recommendations in a more political environment) and final decision-making. If so, the appraisal (documentation) is rarely publicly accessible. Many, though not all, committees lay down transparent appraisal criteria in considerable detail (Model: OHTAC/Ontario or NSC/UK), sometimes criteria are general in nature (Model: G-BA/Germany), some committees strive towards operationalization (Model: ELGK/Switzerland). How criteria are weighted against each other is only rarely addressed explicitly, and if, only cursory.

Options to consider:

- ✿ Establishment of transparent appraisal process (criteria for composition of committee-members, terms of reference for decision-making, CoI-management, appraisal criteria, procedural rules etc.)
- ✿ Consensual appraisal (discussion) of HTA and recommendation to decision-maker. Ev. documentation of argument in case of deviation from assessment.



### Excursus: Beyond static HTA reports: Ontario's Evidence Review Process

In 2003 the Canadian province Ontario started to develop a single portal for the uptake and diffusion of health technologies based on an approach that is evidentiary, bottom-up, transparent, accountable and open to appeal [50]. Health interventions reviewed include a wide range of procedures, services, and devices. Applications for conducting a review are accepted from all interested parties, including patients and members of the public. Broad stakeholder engagement via a professional and public consultation process, in which recommendations are open for comment, is encouraged. When there is insufficient evidence on the safety, the effectiveness and/or the cost-effectiveness of a health intervention, a so called “field evaluation” designed to inform policy and funding decisions prior to making long-term commitments is commissioned. [51, 52]. Figure 3.5-4 illustrates Ontario's Evidence Review Process.

single portal for uptake of health technologies

applications for reviews from all stakeholders

largest program in the world for generating real-life evidence through “field evaluations”

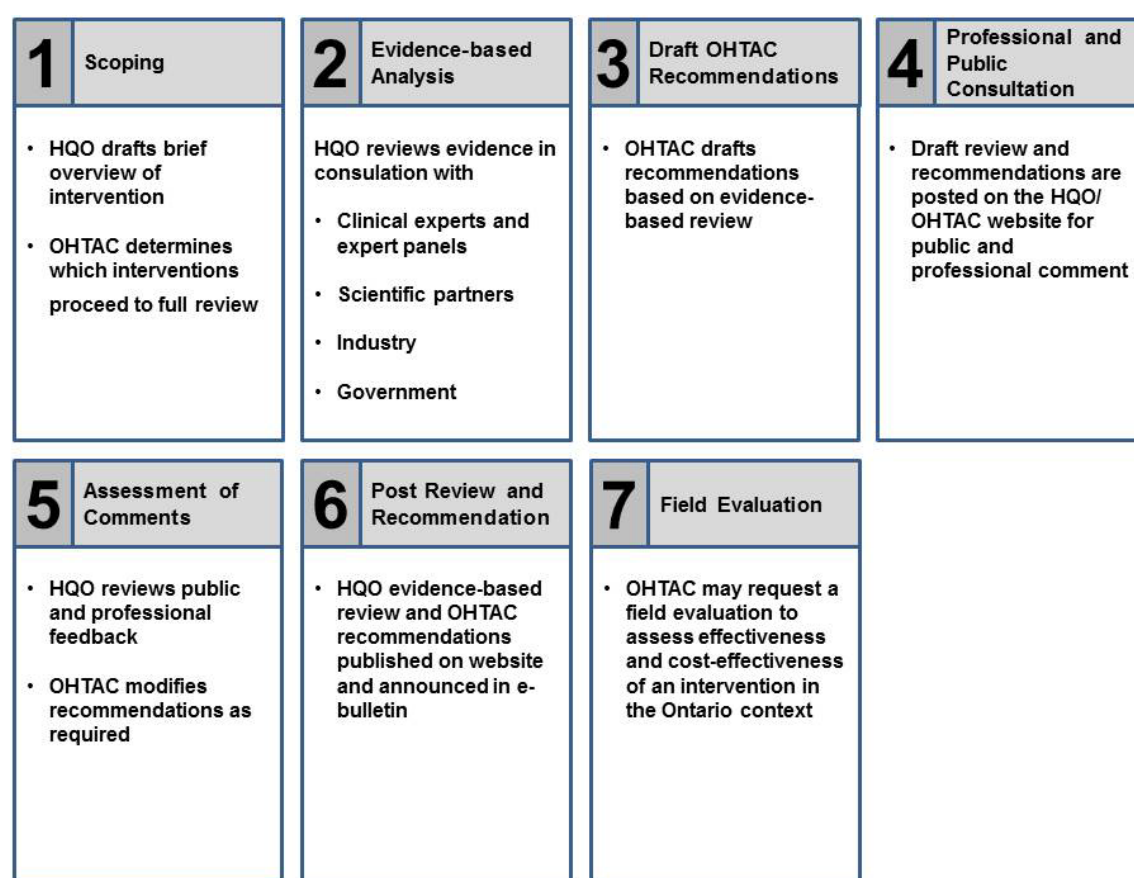


Figure 3.5-4: Ontario Evidence Review Process. Source: [53]

Abbreviations: HQO ... Health Quality Ontario,

OHTAC ... Ontario Health Technology Advisory Committee

Ontario's evidence review process has changed the way policy makers view and use health technology analyses. As opposed to the traditional static HTA report that does not address the needs of decision makers, the Ontario process is seen as more relevant, responsive and dynamic [51].

evidence review process actually addresses needs of decision makers

legitimization for HTA  
guarantee of benefits  
for more efficient use of  
resources

### Evaluation of impact

To legitimize – publicly financed – HTA research, as well as to guarantee benefits of HTA research and to prioritize future research, there is need to evaluate whether the work thus far has had an impact on the national health care system. The HTA research should ultimately result in more efficient use of resources and it should support the sustainability of a public health care system. Not least, HTA intends to contribute to improved population health. It is therefore an inherent characteristic of HTA that the research results and its ‘products’ are to be used by the defined target groups [54, 55].

broad definition  
of impact  
increase of efficient  
resource-use, but also  
increased public  
understanding

Conceptual frameworks for impact-evaluations propose that impact is defined broadly: not only economic impact on decreased expenditures due to HTA recommendations and the use of HTA for investment and reimbursement decisions, but also overall increased knowledge about evidence-based medicine and an “HTA culture” (e.g. in media reporting of new interventions, in public demand for evidence for investments, distinction between consensus-based and evidence-based clinical guidelines) might be the influence of HTA [56].

### “Good practice” HTA products for the assessment of medical devices: 4 examples

#### *mini-HTA, Denmark [15]*

Danish mini-HTA  
format geared towards  
decision situation in a  
hospital under time  
constraint

easily incorporated  
into hospital planning  
processes

In cooperation with local HTA environments a flexible decision support tool was developed for the use of hospital management when contemplating the introduction of a new health technology. A mini-HTA can easily be incorporated into budget and planning processes. A mini-HTA consists of a form and an accompanying guide. The form, or quick check list, contains 26 questions concerning the prerequisites for and consequences of using the new health technology. The questions are grouped into the five domains “Introduction” (e.g. “Who is the proposer (hospital, department, person)?”), “Technology” (e.g. “On which indication will the proposal be used?”), “Patient” (e.g. “Does the proposal imply any risks, adverse effects or other adverse events?”), “Organisation” (e.g. “Has the proposal been implemented in other hospitals nationally or internationally?”) and finally “Economy” (e.g. “Are there any start-up costs of the equipment, rebuilding, training etc.?”). The answers to the questions provide a brief basis for decisions (2-5 pages) and take 1-2 days to complete (excluding time spent on information retrieval and assessment, as well as time for economic calculations). A mini-HTA offers decision support for a specific environment very quickly.

#### *Systematic reviews supporting the annual update of a national inpatient case-mix funding system, Austria [13]*

annual assessments of  
interventions for update  
of Austrian hospital  
benefit catalogue

Each year, the federal ministry of health receives suggestions for new medical interventions to be reimbursed within the national inpatient case-mix funding system. These interventions are prioritized by the ministry and contracted out for assessment to an independent HTA agency. The efficacy and safety of these interventions are assessed in systematic reviews. Each contains a summary of the scientific evidence according to the GRADE scheme and a recommendation. The production and external review takes four months. These documents are available online in English.

***Traffic light symbols of the MUMM program, Finland [16]***

The collaborative MUMM program between the Finnish national HTA agency and Finnish hospital districts was started in 2006 to offer critically appraised decision support on effectiveness, safety and costs based on a systematic search of the literature. A secondary aim of MUMM is to foster evidence based practice in Finnish hospital. A MUMM review group consists of up to three clinical experts and up to three HTA agency staff. MUMM uses the traffic light model (compare Figure 3.5-5 below) to express the results of a review in the form of a direct recommendation: use (green), conditional use (orange), do not use (red).

**communication tool  
for hospital-based HTAs  
in Finland**

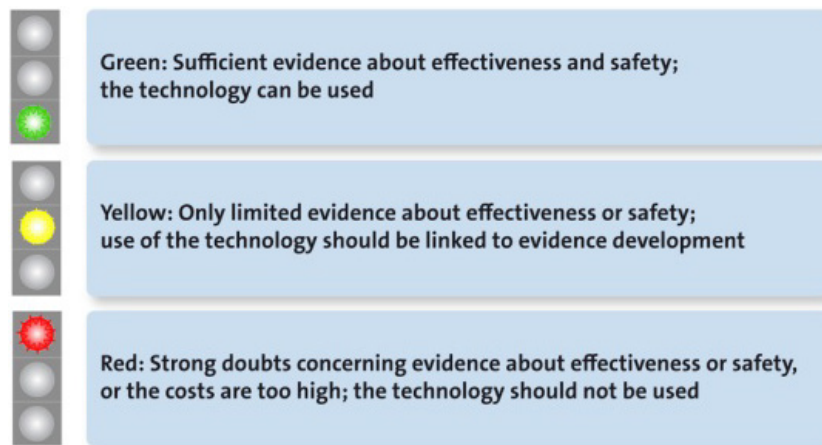


Figure 3.5-5: Traffic light symbols for direct recommendation, source: MUMM, Finland

This form of presentation gained wide attention in the Finnish health care system. People who do not directly know of the MUMM program or of HTA can be found talking about “green lights” or “yellow lights” or “red lights”. Only the abstracts of the Finnish MUMM reviews published since 2007 are available in English online. [57]

***Comparison of competing technologies via Matrix4Value, Spain [58]***

Matrix4Value is a decision-support tool developed by Hospital Clinic of Barcelona for prioritizing new competing health technologies after their assessment using the mini-HTA approach. An overall score for each health technology is calculated and then plotted in a value/risk matrix. By visually showing how health technologies are placed relatively to each other in a risk-value matrix, this tool assists the decision-making process. It provides more clear-cut information for the prioritization of health technology investments under a fixed budget scenario prevalent in hospital settings. Table 3.5-1 below illustrates exemplary values for a certain medical device in comparison to a competing technology.

**Spanish tool to compare  
health technologies for  
hospitals competing for  
a limited budget**

Table 3.5-1: Exemplary values for a certain medical device, source: Matrix4Value [58]

| Value                           |                     |
|---------------------------------|---------------------|
| Safety                          | Better              |
| Efficacy/Effectiveness          | Equal               |
| Impact on patient               | Better              |
| Cost-effectiveness is available | Yes                 |
| Quality of evidence             | Moderate-low        |
| Innovativeness degree           | Moderate            |
| Risk                            |                     |
| Impact on staff                 | Less staff required |
| Impact on physical space        | Not applicable      |
| Impact on health care           | Moderate            |
| Incremental cost                | Lower               |
| Net cost                        | Not applicable      |
| Investment effort               | High                |

### 3.5.2 Analysis of HTA processes (and products) in Lithuania

divided responsibilities  
for HTA  
... medical devices:  
SHAA  
... public health: IoH

As stated earlier in more detail (see description in 3.1.2.2), the responsibility for producing HTAs lies with authorities under the MoH: SHAA for medical devices and IoH for public health. For pharmaceuticals SMCA is at this stage not active in producing HTAs. SHAA has laid out internal procedures for HTA. In a current EU project capacity for HTA is being built at SHAA. The development of IoH's internal procedures for HTA is presently being finalized in a second EU project for capacity building for HTA, this time at IoH.

#### *Topic identification and prioritization*

HTAs for medical  
devices: manufactures  
set most topics through  
applications ...  
MoH influences  
prioritization

SHAA conducts its HTAs on medical devices (so far 2 completed and 4 ongoing) mostly following an application by a manufacturer but also on topics suggested by the MoH and by the National Cancer Institute. IoH identified the topics for its first HTA reports on public health topics (so far 3 completed and 2 ongoing) through an internal pilot process that included prioritization of topics. Also the MoH suggested topics for public health HTAs.

#### *Deliberation on HTAs and decision on implementation*

HTAs submitted to MoH  
HTA Committee for  
deliberation  
  
Minister decides on  
implementation

SHAA's HTA Commission has in practice not been meeting for some time. HTAs produced by SHAA are in fact submitted directly to the MoH HTA Committee, which can make recommendations to the Minister. The Minister can decide on steps towards the implementation of results from an HTA. Also the applying manufacturer receives the SHAA HTA on its medical device. HTAs produced by IoH are currently also submitted directly to the MoH HTA Committee.

***Evidence component in pharma-reimbursement***

While Lithuania at present undertakes no HTA activity in the narrower sense for pharmaceuticals, an established process with a clear structure for the application of a pharmaceutical for NHIF reimbursement (positive list) has been in place for over a decade. This process instituted a mandatory pharmacoeconomic evidence component. The applicant submits the dossier to the MoH (Pharmaceutical Reimbursement Commission and Compulsory Health Insurance Council). The dossier includes a pharmaco-economic report, commissioned externally by the applying pharmaceutical company itself. The two bodies deliver separate reimbursement recommendations to the Minister, who takes the final decision. The HTA processes for medical devices and public health and the evidence component in reimbursement decisions for pharmaceuticals described above are illustrated in Figure 3.5-6 below.

**process of application for reimbursement of pharmaceuticals (positive list) has evidence based component: pharmacoeconomic analysis**

**company directly pays experts**

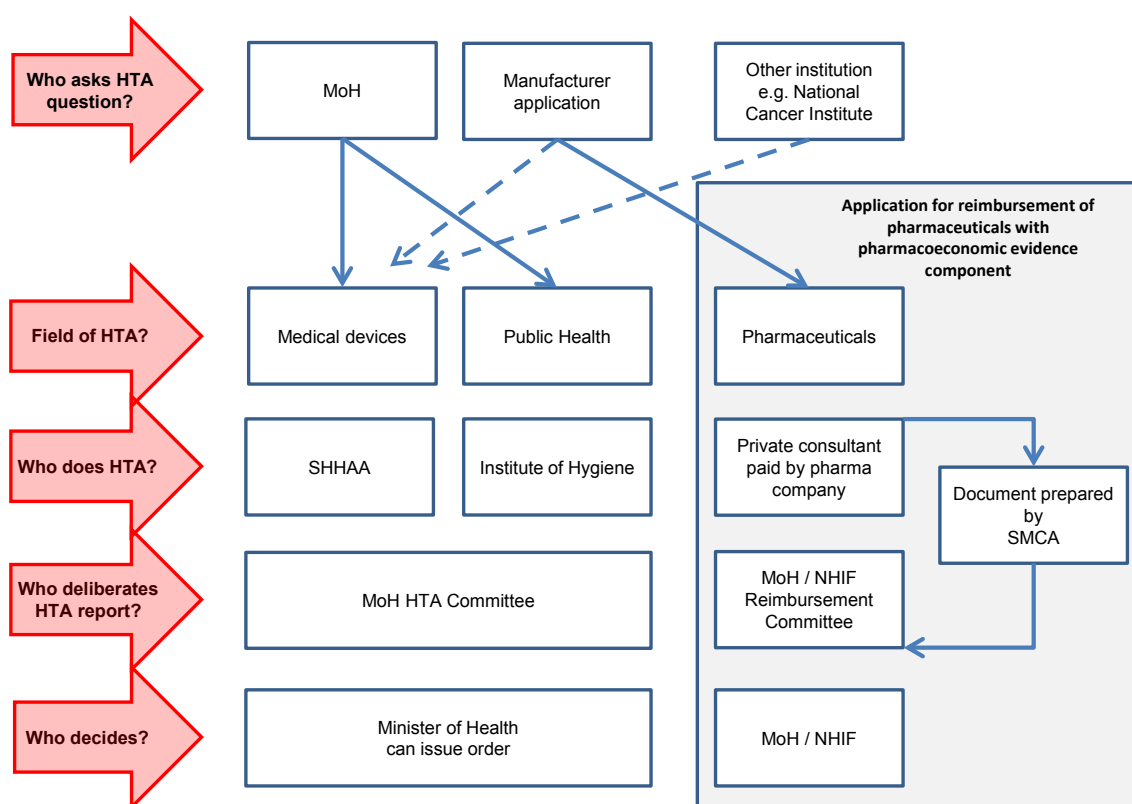


Figure 3.5-6: HTA processes in Lithuania

*Deficiencies*

**Lithuania has no  
coordinated HTA process  
in place**

**no criteria for topic  
selection of HTAs**

**no quality criteria  
for HTAs**

**independence of HTA  
doers from MoH policy  
makers uncertain**

**second potential user of  
HTAs for reimbursement  
decisions NHIF only  
weakly involved**

**no clear pathway  
from HTA to possible  
implementation of  
results**

Currently Lithuania lacks a transparent and coordinated process for HTA. The independence (see description of independence in 3.3.1) of HTA doers from policy makers and from potentially conflicting regulatory functions located at their organization (e.g. SHAA) is currently not safeguarded. The role of HTA in informed decision-making is not defined. There are no effective criteria in place for when to conduct an HTA (e.g. ahead of planned investment in a medical device costing above a certain threshold). For medical devices there is no detailed planning document for expensive medical devices (number and location of PET, MRI, CT etc.) based on evidence from HTAs that would yield an explicit guideline for investments. While one potential key beneficiary of evidence based decision support through HTA in Lithuania, the MoH, has an active say in the choice of topics for HTAs for medical devices and for public health, the other, NHIF, is not directly involved at all.

For medical devices there is no proactive public interest agenda setting for HTA topics (e.g. horizon scanning and disinvestment) and for pharmaceuticals there is none for the current reimbursement system (e.g. identification of candidates for removal from positive list); instead manufacturers play the key role in determining the HTA topics. Currently broader health care system level topics (e.g. concentration of neurosurgery or of specialized cancer services in centers of excellence) are not addressed through HTAs. There is no coordination in place between the doers of HTA (currently SHAA and IoH, in the future supposedly also SMCA). SHAA and IoH do not cooperate on topics that transcend their responsibilities for medical devices and public health respectively. Safeguards for the quality of HTA reports are not established. There is no clear pathway from completion of an HTA report towards a decision on implementation (or not) and then on to implementation. While the process of application for reimbursement of pharmaceuticals by NHIF is explicit and clear, the quality of the evidence-based component and the transparency of the ensuing decision making are not. Pharmaceutical companies currently pay experts they themselves select to compile the required pharmaceutical-economic report.

## 4 Summary and Discussion

### *Legal framework and regulatory context of decision-making*

The regulatory environment for decision-making in health care is essential for the actual role of HTA. In most countries, binding legal requirements to consider scientific evidence of effectiveness, safety or cost-effectiveness before a decision on Public Health investments, on new equipment or benefit-catalogues is made are rare. Nevertheless, HTA has the greatest impact if it is carried out for a concrete policy decision. Most HTA agencies in Europe are advisory bodies and have no regulatory function in order to safeguard the independence of HTA from vested interests.

Lithuania's health system with a single social health insurance fund is highly centralized. The MoH has the key role and many decisions are ultimately taken by the minister of health. The MoH also administers EU structural funds, which account for 60% of capital investment in the health sector. Forward looking health policy documents passed by Parliament stabilize governance.

The introduction of HTA into decision-making processes has been initiated several times (1993, 1999), though has not been successful. Prioritization of health resource allocation is still mostly based on a politically driven, rather than evidence-based, decision-making process.

HTA activities are in their early stages and fragmented.

### *Utilization (need and demand) of HTA in health care and barriers*

Technology assessments are useful to a wide range of decision-makers in health care, including government policy makers and social health insurance administrators, for the following:

- ✿ Decision to include or exclude an intervention (drug, procedure, device) in benefit catalogue or positive/negative list.
- ✿ Decisions on disinvestment from interventions that are obsolete or unsafe or of uncertain benefit.
- ✿ Decisions on planning and localization of an expensive device (e.g. PET) or a specialized service (e.g. neurosurgery).
- ✿ Decisions on quality improvement through HTA input for clinical pathways, evidence-based guidelines and development of quality indicators for patient relevant outcomes.

In order to support decision-makers, the relevant HTA needs to be of good quality (valid, reliable, with a clear message) and available on time for the decision. HTA should fulfill a bridge function between science, policy making and practice. For this HTA does have to understand the needs and priorities of policy makers. In the same way policy makers have to be familiar with and open to the potential of evidence to inform decisions. Human and financial resources need to be available to produce the relevant HTA reports in good quality. Barriers to the utilization of HTAs include a resistance to a transition from "eminence based" to "evidence based" decision-making coming from professional (clinical) bodies, from management or from policy makers.

regulatory environment  
for role of HTA essential,  
most impact of HTA  
if conducted for  
concrete decisions  
HTA: only advising  
health policy; deciding

Lithuania:  
highly centralized  
decision-making  
MoH main  
decision-maker

efforts to introduce HTA  
already in 1993 and 1999

2015: some HTA  
activities in early stage

wide range of  
applications of HTA

benefit-catalogues+  
positive lists

planning + localization  
of specialized services

quality improvement

to overcome barriers in  
the actual use of HTAs:

timely HTAs of good  
quality with clear  
messages are important

potential resistance  
from clinicians



|  |  |
|--|--|
| <p>Lithuania: in need to allocate the limited financial resources</p> <p>need to support decisions on investments in PH-programs and specialized services (planning) + for benefit-catalogue (drugs + devices)</p> | <p>Lithuania is understood to need a rational system of decision making on investment and reimbursement that includes an HTA function. There are primarily two institutions that require decision support for the allocation of their limited financial resources for reimbursement and investment: MoH and NHIF. When reimbursing a medical device or pharmaceutical, the NHIF also needs to determine at what stage of the life-cycle of a technology (early on or later) to include it in the benefit catalogue. To make it onto the positive list of NHIF reimbursed pharmaceuticals, an evidence based pharmaco-economic dossier is required as part of the application process. When the MoH is implementing strategies or programs, like the current EU funding program with its special focus on public health and investment in evidence based practice, the MoH requires decision support for determining which measures are best suited for the task.</p> |
| <p>barriers:</p> <p>clear and transparent HTA process</p> <p>independence of HTA producers from policy</p>   | <p>Barriers for HTA in Lithuania are the lack of a clear and transparent HTA process (coordination of HTA demand and production, proactive prioritizing of HTA topics, quality criteria for HTAs, clear pathway towards implementation) and the compromised independence of HTA doers from policy makers, regulators and industry. The value of HTA needs to be appreciated by the political echelon.</p>  |
| <p>no ONE "best practice model" of HTA institutionalization: many forms of organizations</p>   | <p><b><i>HTA institutionalization and financing</i></b></p> <p>There is no one "best practice model" of HTA institutionalization in Europe. HTA can be located at a single centralized HTA agency or there can be decentralized and regionalized HTA institutions. Some countries organize their HTA activities in coordinated networks of HTA doers. Most institutions are publicly funded and closely associated with government, ministries of health or social health insurance. Some institutions are academic.</p>   |
| <p>credibility of HTA depends on independence from interest groups</p>   | <p>The credibility of HTA depends on independence from interest groups while at the same time maintaining close contact with decision makers (see description of independence in 3.3.1). For this, stable long term funding of HTA activities and mechanisms against political interference are essential.</p>   |
| <p>critical requirements: stable funding several mechanisms to safeguard independence</p>  | <p>In the process of developing a national HTA infrastructure, there is a need to "organize" these critical requirements and to secure independence by setting up adequate governance structures. The independence from policy makers and special interests is regulated in most countries. Mechanisms to safeguard independence include clear and transparent process descriptions, the monitoring of the scientific quality of HTAs, external peer-review for all HTA products and the separation of recommendations based on an HTA and the policy decision.</p>  |
| <p>Lithuania: 2 institutions conducting HTA</p> <p>SHAA: Medical Devices</p> <p>IoH: Public Health Interventions</p> <p>HTA Committee since 2014 for coordination</p>  | <p>HTA activities in Lithuania are fragmented. An independent HTA institution has never been established. Two institutions under the MoH currently perform HTAs exclusively on medical devices (SHAA is currently working on 4 topics, having completed 6) and HTAs on public health issues respectively (IoH is currently working on 2 topics, having completed 3). Temporary funding for HTA capacity building at SHAA and IoH comes from two EU projects (2013-2015). HTA features both in the current National Health Program adopted by Parliament and in the present government's action plan. The MoH established an HTA Committee in 2014 to coordinate HTA activities, to develop a system for the prioritization of health technologies to assess, to examine completed HTA reports and to give recommendations to the minister of health on implementation.</p>   |



***Human resources for HTA and capacity building***

Decision-making about the adoption of new technologies is part of the operational routine of health authorities, funders and service providers. These decisions are frequently based on unilateral information from a single expert or from industry. The challenge is to change the decision-making culture towards evidence-based decisions. This change requires – beside the firm commitment from health policy (health authorities) – sufficient national capacities to carry out HTA and implement it: HTA core staff (systematic literature search, critical appraisal of studies, evidence synthesis), training to understand and implement HTA for policy makers, clinicians and health care managers plus academic research capacity in HTA methodologies. HTA is by definition multidisciplinary and needs to bring together experts from many fields.

For small countries strong external HTA-networks (EUnetHTA) and partner-institutions are important, to increase the national efficiency by collaborating in joint assessments and by building upon other HTA-agency's outputs.

In Lithuania there is only limited capacity building for HTA outside of the two ongoing projects funded by the EU (2013-2015) for SHAA and IoH. But the role of e.g. the LUHS in providing training on HTA (critical appraisal for systematic reviews, economic evaluation, etc.) is essential. In the future a considerable challenge for Lithuania will be to retain trained HTA experts in the public sector (and even in the country).

***HTA processes and products, special focus assessment of medical devices***

To bridge the domains of medical research and health policy-making, HTA offers a clear structure for transparent processes and products. This transparency is of utmost importance to make the results valid, reliable and open to scrutiny. All along this process, HTA transparently discloses its methods, including those for the management of conflict of interest to avoid undue influence from special interests and those for public consultation and stakeholder involvement.

An HTA is initiated either through the identification of an assessment need in the health system (e.g. by the MoH or by social insurance) or through the submission of an assessment request by an applicant (e.g. manufacturer of a medical device), most HTA regimes combine the two. Priorities for the commissioning of HTAs have to be set, and often aim to identify high volume and high cost interventions with a high amount of uncertainty. Next the prioritized policy question that reflects the context in which the assessment is carried out is translated to a research question that can give an evidence-based answer to the policy problem. An evidence analysis of safety and effectiveness may be sufficient for rapid assessments of single technologies (drugs, medical devices). Comparing multiple technologies or comprehensive assessments of complex interventions in addition require information on psychological/social/ethical implications, on organizational effects and on economic impact. For each of these domains the quality of the available evidence is appraised, the evidence is extracted and patient relevant outcomes are synthesized. Before the publication of an HTA report, peer review as an external quality control is considered essential. A key, often underestimated activity is the dissemination of HTA products. During the appraisal of the evidence synthesized, it is contextualized and recommendations are derived. The European HTA cooperation EUnetHTA produced templates for processes and products of good HTA practice.

**challenge to change the decision-making culture towards evidence-based decisions**

**sufficient national capacities for HTA production also: training for decision-maker**

**strong external networks and collaborations**

**Lithuania: only some capacity due to EU-projects great potential in academia**

**transparency of HTA process and products of utmost importance: results must be valid, reliable and open to scrutiny**

**Steps in the process:**

- \* identification of relevant topics
- \* prioritization
- \* scoping (transferring the policy question into a research question)
- \* evidence analysis
- \* peer-review
- \* dissemination
- \* appraisal
- \* recommendations

**good practice: EUnetHTA process and products**

|  |   |
|--|---|
| <p><b>Lithuania:</b><br/> <b>SHAA: manufacturer-</b><br/> <b>based topic selection</b><br/> <b>IoH: MoH selects topics</b></p>         | <p>In Lithuania HTA is only in its infancy. SHAA, an institution under the MoH, conducts HTA on medical devices, mostly following an application by a manufacturer. IoH, another institution under the MoH, is responsible for HTAs on public health topics. There is presently no HTA activity beyond medical devices and public health. The resulting HTA reports are mostly suggested by the MoH. These HTA reports are submitted to the MoH HTA Committee that can make recommendations to the minister, who ultimately decides on implementation measures. A coordinated HTA process for Lithuania is not in place yet, neither are there explicit criteria for topic selection for HTAs, nor for the quality of HTA reports. The independence of HTA doers from policy makers and from potentially conflicting regulatory functions at their organization (e.g. in the case of HTA on medical devices at SHAA that is responsible for regulating medical devices) is currently not safeguarded. There is as yet no clear path from HTA towards implementation of recommendations. NHIF, the main funder of health-care services in Lithuania and as such potentially a major user of HTA results, is presently only peripherally involved in HTA processes through membership in the MoH HTA Committee.</p> |
| <p><b>MoH HTA Committee</b><br/> <b>makes</b><br/> <b>recommendations based</b><br/> <b>on (SHAA+IoH) HTAs</b></p>                     |   |
| <p><b>no process for</b><br/> <b>prioritization, quality</b><br/> <b>assurance, safeguarding</b><br/> <b>independence in place</b></p> |   |
| <p><b>MoH-centered activities</b></p>  |   |

## 5 Conclusion and Recommendations

The recommendations developed (and activities proposed) based on this report are published in a separate document:

“HTA-Strategy for Lithuania” (<http://eprints.hta.lbg.ac.at/1064>).

They should be considered as a *contribution* to the Lithuanian HTA-Strategy. The ultimate success of the HTA-Strategy is strongly dependent on if and how Lithuanian health sector stakeholders take the ownership of the Strategy and establish a process for evidence-based decision support.

**recommendations  
published in separate  
document**

**should be considered  
contribution (only)**



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